

1 UNITED STATES DISTRICT COURT  
2 SOUTHERN DISTRICT OF WEST VIRGINIA  
3 AT CHARLESTON  
4 IN RE: ETHICON, INC., Master File No.  
PELVIC REPAIR SYSTEM 2:12-MD-02327  
5 PRODUCTS LIABILITY MDL No. 2327  
LITIGATION Joseph R. Goodwin  
6 \_\_\_\_\_ U.S. District Judge

THIS DOCUMENT RELATES  
7 TO:  
All Wave II TVT Cases  
8 Jean Fleck v. Ethicon,  
Inc., et al.  
9 Case No. 2:12-cv-01681  
10 Phyllis Martin v.  
Ethicon, Inc., et al.  
11 Case No. 2:12-cv-02029  
12 Ramona Phillips v  
Ethicon, Inc., et al.  
13 Case No. 2:12-cv-02143  
~~~~~

14  
15 VIDEOTAPED DEPOSITION OF  
16 JANET TOMEZSKO, M.D.  
17 June 27, 2016  
18 8:07 a.m.  
19 9599 Skokie Boulevard  
20 Skokie, Illinois  
21  
22  
23 Deanna Amore, CSR, RPR, 084-003999  
24

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ALSO PRESENT:

Milo Savich, Legal Video Specialist

Janet Tomezsko, M.D.

|    |                                    |                         |             |
|----|------------------------------------|-------------------------|-------------|
| 1  | I N D E X                          |                         |             |
| 2  | WITNESS                            |                         | EXAMINATION |
| 3  | JANET TOMEZSKO, M.D.               |                         |             |
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| 9  | NUMBER                             | DESCRIPTION             | PAGE        |
| 10 | Exhibit 1                          | TVT Expert Report of    | 8           |
| 11 |                                    | Janet E. Tomezsko, M.D. |             |
| 12 | Exhibit 2                          | Curriculum Vitae of     | 8           |
| 13 |                                    | Janet E. Tomezsko, M.D. |             |
| 14 | Exhibit 3                          | Reliance List of        | 9           |
| 15 |                                    | Materials Referenced    |             |
| 16 | Exhibit 4                          | Notice of Video         | 11          |
| 17 |                                    | Deposition of Dr. Janet |             |
| 18 |                                    | Tomezsko, M.D.          |             |
| 19 | Exhibit 5                          | Case Materials Binder   | 13          |
| 20 | Exhibit 6                          | 6.1.2016 Invoice        | 17          |
| 21 | Exhibit 7                          | 2008 Gynecare TVT       | 73          |
| 22 |                                    | Instructions for Use;   |             |
| 23 |                                    | ETH.MESH.02340504-533   |             |
| 24 |                                    |                         |             |

|    |            |                          |      |
|----|------------|--------------------------|------|
| 1  | EXHIBITS   |                          |      |
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| 3  | Exhibit 8  | 1.9.2012 E-mail;         | 103  |
| 4  |            | ETH.MESH.08421479        |      |
| 5  | Exhibit 9  | 6.26.2006                | 105  |
| 6  |            | Ethicon-Approved Product |      |
| 7  |            | Pointer Gynecare TVT;    |      |
| 8  |            | ETH.MESH; 00167119       |      |
| 9  | Exhibit 10 | Pore Size Table;         | 112  |
| 10 |            | ETH.MESH.05479535        |      |
| 11 | Exhibit 11 | 1.29.2009 E-mail         | 129  |
| 12 |            | Exchange;                |      |
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| 18 | Exhibit 14 | 14A - TVT (PM) Videos;   | 182  |
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| 20 |            | 14C - Tomezsko General   |      |
| 21 |            | Materials;               |      |
| 22 |            | 14D - Unspecified        |      |
| 23 |            |                          |      |
| 24 |            |                          |      |

1 THE VIDEOGRAPHER: We are now on the  
2 record.

3 My name is Milo Savich, and I am a  
4 videographer for Golkow Technologies.

5 Today's date is June 27, 2016, and time is  
6 8:07 a.m.

7 This video deposition is being held in  
8 Skokie, Illinois, in the matter of In Re: Ethicon  
9 Inc., Pelvic Repair System Products Liability  
10 Litigation, which is being heard in the  
11 United States District Court, Southern District of  
12 West Virginia, Charleston Division. The case  
13 number is 2:12-MD-02327.

14 The deponent is Dr. Janet Tomezsko.

15 Will counsel please identify themselves  
16 for the record.

17 MR. JACKSON: Tim Jackson, Wexler Wallace, on  
18 behalf of the plaintiffs.

19 MR. SNELL: Burt Snell, representing  
20 Johnson & Johnson and Ethicon.

21 THE VIDEOGRAPHER: The court reporter is Deanna  
22 Amore, who will now swear in the witness, and we  
23 may then proceed.  
24

1 (Whereupon, the witness was  
2 duly sworn.)

3 THE WITNESS: I do.

4 MR. JACKSON: Good morning, Doctor.

5 THE WITNESS: Good morning.

6 MR. JACKSON: Could you please state and spell  
7 your name for the record.

8 THE WITNESS: Janet Tomezsko, T-o-m-e-z-s-k-o.

9 MR. JACKSON: And, Dr. Tomezsko -- am  
10 I pronouncing that correctly?

11 THE WITNESS: That's correct.

12 MR. JACKSON: As I introduced myself before we  
13 got on the record, my name is Tim Jackson, and I'm  
14 from a firm called Wexler Wallace here in Chicago;  
15 do you understand that?

16 THE WITNESS: Yes.

17 MR. JACKSON: And you're here today to give  
18 testimony about the general TVT report you wrote in  
19 this case; is that correct?

20 THE WITNESS: Yes.

21 MR. JACKSON: And you also wrote three separate  
22 plaintiff-specific reports related to this case; is  
23 that correct?

24 THE WITNESS: Yes.

1 MR. JACKSON: And we'll be addressing some of  
2 those later today; is that your understanding?

3 THE WITNESS: Yes.

4 MR. JACKSON: And is there any reason you feel  
5 you cannot testify fully and accurately today?

6 THE WITNESS: No.

7 MR. JACKSON: And if I ask something and it's  
8 not clear what I'm asking, I'll ask that you let me  
9 know that so I can rephrase it; is that fair?

10 THE WITNESS: Yes.

11 MR. JACKSON: And if I ask a question and you  
12 answer it, is it fair for me to assume that you  
13 understood the question?

14 THE WITNESS: Yes.

15 JANET TOMEZSKO, M.D.,  
16 called as a witness herein, having been first duly  
17 sworn, was examined and testified as follows:

18 EXAMINATION

19 BY MR. JACKSON:

20 Q. Have you ever had your deposition taken  
21 before?

22 A. Yes, I have.

23 Q. Okay. In what context?

24 A. Subsequent treater.

1 Q. And about how many times?

2 A. I think three or four.

3 Q. And are there any other times you've been  
4 deposed?

5 A. No.

6 (Whereupon, TOMEZSKO Exhibit 1  
7 was marked for identification.)

8 BY MR. JACKSON:

9 Q. I'm going to hand you what we've premarked  
10 as Exhibits 1 through 3.

11 If you could just confirm that Exhibit 1  
12 is an accurate copy of the ex -- the general TVT  
13 report you provided in this case?

14 A. It appears to be, yes.

15 Q. And if you could look at Exhibit 2,  
16 please.

17 (Whereupon, TOMEZSKO Exhibit 2  
18 was marked for identification.)

19 BY MR. JACKSON:

20 Q. And can you just confirm that looks like  
21 an accurate copy of the CV that would have been  
22 submitted with your report?

23 A. Yes, it does.

24



1 (Whereupon, TOMEZSKO Exhibit 3  
2 was marked for identification.)

3 BY MR. JACKSON:

4 Q. And if you could just look at Exhibit 3  
5 and confirm that that looks like an accurate copy  
6 of the reliance list that was provided with your  
7 report in this case.

8 A. I think we might have a more up-to-date  
9 one.

10 Q. Okay. But is it your understanding that  
11 that's the one that would have been submitted with  
12 the report?

13 A. Originally, yes.

14 Q. Okay. Thank you. Thank you.

15 And, Doctor, did you review prior to the  
16 deposition today?

17 A. Yes, I have.

18 Q. And what did you review specifically for  
19 this deposition?

20 A. I reviewed the general medical literature,  
21 literature regarding urinary incontinence  
22 treatment, TVT-specific literature.

23 I have reviewed the testimony of medical  
24 experts for the cases.

1 I have reviewed some Ethicon documents and  
2 then patient-specific data, but that's not for this  
3 report.

4 Q. Okay. And did you speak with anyone prior  
5 to your deposition today specifically in regards to  
6 the deposition?

7 MR. SNELL: Objection. Form. Vague.

8 Go ahead.

9 THE WITNESS: Yeah, that's very vague. Can you  
10 clarify? Do you mean when the deposition was or...

11 BY MR. JACKSON:

12 Q. Did you -- strike that.

13 You met with your attorney in preparation  
14 for the deposition today, correct?

15 A. Yes.

16 MR. SNELL: Objection. Form. I'm not her  
17 attorney.

18 THE WITNESS: Oh, that's true. Sorry.

19 BY MR. JACKSON:

20 Q. Did you meet with an attorney for Ethicon  
21 in preparation for this deposition today?

22 A. Yes.

23 Q. And how many times did you meet?

24 A. Two times.

1 Q. Okay. And for about how long total?

2 A. That's a good question. Probably about  
3 eight or ten hours.

4 (Whereupon, TOMEZSKO Exhibit 4  
5 was marked for identification.)

6 BY MR. JACKSON:

7 Q. I'm going to hand you what's been marked  
8 Exhibit 4, and this is the notice of the deposition  
9 today.

10 A. Yes.

11 Q. Have you seen that document before?

12 A. Yes, I have.

13 Q. Okay. And I see you brought some  
14 documents with you. Are you bringing those in  
15 response to the document request in the deposition  
16 notice?

17 A. These are the documents that go along with  
18 my general report.

19 Q. Okay.

20 A. And I don't have any other -- they are  
21 just all the literature.

22 Q. Okay. So I see one -- one large binder on  
23 the desk in front of you. Could you just generally  
24 tell me what's in that? You mentioned literature.

1           A.     Right.  So this is -- this is my -- my  
2     CV -- my report, my CV, the materials list and then  
3     part of the literature that I reviewed.

4           Q.     Okay.  When you say "part of the  
5     literature that you've reviewed," are there other  
6     documents you reviewed that are not included in  
7     this binder?

8           A.     Yes, there are many.

9           Q.     So how did you choose which documents to  
10    include in this binder?

11          A.     We narrowed it down to include the ones  
12    that were most pertinent and most referenced in  
13    this document.  We can't include all of them  
14    because there are thousands of them.  So the ones  
15    that are most relevant and most pertinent, the  
16    Level 1 data.

17          Q.     And, Doctor, when you say "Level 1 data,"  
18    what do you mean by that?

19          A.     That is the peer-review classification,  
20    Level 1 data is the meta-analysis, systematic  
21    reviews of randomized controlled trials considered  
22    the highest level data to base clinical opinions  
23    on.

24          Q.     Okay.  And can we go ahead and we'll mark

1 the binder she brought with her as Exhibit 5, if  
2 that makes sense.

3 (Whereupon, TOMEZSKO Exhibit 5  
4 was marked for identification.)

5 BY MR. JACKSON:

6 Q. Doctor, can you tell me when were you  
7 first contacted about providing a report in this  
8 case?

9 A. Oh, several months ago.

10 Exactly when? The date?

11 Q. I mean, could you give me a guess of  
12 approximately which month?

13 A. February-March.

14 Q. Okay.

15 MR. SNELL: Counsel, can I make a statement for  
16 the record?

17 MR. JACKSON: Sure.

18 MR. SNELL: Your question about what she  
19 brought, you were directing her attention to that  
20 big binder. She did bring other stuff in response.

21 MR. JACKSON: Okay.

22 MR. SNELL: I just didn't want there to be --  
23 the record to be unclear because we all know that  
24 there are multiple boxes sitting over in the corner

1 and things. So if your question was limited to  
2 that, she's answered it, but if you want to know  
3 the entirety of everything she brought, it's here  
4 for you to look at or ask her about. I just want  
5 to make sure there was no unclarity on the record.  
6 BY MR. JACKSON:

7 Q. Okay. Doctor, your counsel for Ethicon  
8 mentioned that there were other boxes brought by  
9 you today; is that correct?

10 A. Yes.

11 Q. And what -- what is in the other boxes?

12 A. So in the entirety of the boxes there are  
13 -- there is more literature. There are IFUs for  
14 the TVT device. There are other Ethicon documents,  
15 and there is the patient's -- patient records that  
16 we need for the later depositions. I have also  
17 thumb drives with data on them, research papers,  
18 et cetera.

19 Q. Okay. And, Doctor, is the entirety of the  
20 materials you've reviewed in connection with your  
21 reports in this case contained in the binder and  
22 the boxes you brought with you today?

23 A. I would say no. I'm sure there is other  
24 documents and literature that I've read that is not

1 included because there is so much volume of  
2 literature I've read through the years, and that is  
3 part of my knowledge.

4 Q. Okay. Thank you.

5 And, Doctor, I believe you stated a moment  
6 ago that you were first contacted about providing a  
7 report in this case in February; is that right?

8 A. Yeah, I think that might be, yes.

9 Q. And at the time you submitted your report  
10 in this case, about how much time had you spent on  
11 that report?

12 A. I would say about 45, 50 hours.

13 Q. Okay. And do you keep track of your time  
14 somewhere?

15 A. Not -- not a detailed track, no.

16 Q. Have you submitted an invoice yet for that  
17 time?

18 A. I have submitted an invoice for part of  
19 the time, yes.

20 Q. Okay. Did you bring any billing  
21 information with you today?

22 A. I have the one invoice.

23 Q. Okay. Is that something you have handy  
24 right now?

1 A. Yes.

2 Q. Okay. Could I take a look at that?

3 A. Forgive me. I have to find it.

4 Can I unclip for a moment?

5 Q. Of course.

6 MR. JACKSON: Let's just go off the record for  
7 a second.

8 THE VIDEOGRAPHER: The time is 8:17 a.m., and  
9 we are going off the video record.

10 (A short break was taken.)

11 THE VIDEOGRAPHER: The time is 8:18 a.m., and  
12 we are back on the video record.

13 BY MR. JACKSON:

14 Q. Doctor, while we were off the record, were  
15 you able to locate the billing information you  
16 brought with you today?

17 A. Yes, I was.

18 Q. And is that something I could take a look  
19 at quickly?

20 A. Yes.

21 MR. JACKSON: Can we go ahead and mark that as  
22 Exhibit 6, please.

23

24



1 (Whereupon, TOMEZSKO Exhibit 6  
2 was marked for identification.)

3 MR. SNELL: What's the date of that?

4 BY MR. JACKSON:

5 Q. Doctor, we've marked as Exhibit 6 a letter  
6 from you to Mr. Burt Snell dated June 1, 2016.

7 It says "I'm submitting this invoice for  
8 my expert witness work from April 1, 2016, through  
9 May 31, 2016. The hours include face-to-face  
10 meeting, phone conversations and record review, all  
11 with an hourly rate of \$400 per hour."

12 Is that your hourly rate?

13 A. Yes, it is.

14 Q. "Total hours for this time period is 45.  
15 Total fee is \$18,000."

16 Did I read that correctly?

17 A. Yes, you did.

18 Q. Okay. Thank you.

19 And so from April 1 to May 31, it looks  
20 like you spent about 45 hours; is that correct?

21 A. Yes.

22 Q. And so you said you would have been first  
23 retained in this case around February?

24 A. You asked me when I was first contacted.

1 Q. When did you first start working on your  
2 report in this case?

3 A. It would have been the beginning of April  
4 then.

5 Q. So that 45 hours is about the entirety of  
6 the time you spent?

7 A. I have -- I'm sure I have spent more than  
8 that.

9 Q. And --

10 A. That does not -- I'm sorry.

11 That does not include recent time.

12 Q. And does that 45 hours include work on  
13 both the TVT general report as well as the  
14 plaintiff-specific reports?

15 A. It does include part of both.

16 Q. Okay. And is it fair to say that since  
17 May 31, you've spent additional time working on  
18 this case?

19 A. Yes, I've spent about another month worth  
20 of work.

21 Q. When you say "about a month worth of  
22 work," approximately how many hours would that be?

23 A. Probably another 40 to 50 hours at least.

24 Q. Okay. Doctor, we have a copy of your CV,

1 so I won't spend an inordinate amount of time on  
2 that, but can you tell me where you went to medical  
3 school?

4 A. I went to Hahnemann University, which is  
5 now known as Drexel University in the Tradition of  
6 Hahnemann and Medical College of Pennsylvania.

7 Q. And where in Pennsylvania is that?

8 A. Philadelphia.

9 Q. And, Doctor, where did you do your  
10 undergrad?

11 A. Penn State.

12 Q. And your residency?

13 A. Lehigh Valley Hospital in Allentown,  
14 Pennsylvania.

15 Q. And what year did you do -- what year was  
16 your residency?

17 A. 1991 to 1995.

18 Q. And did you have a fellowship?

19 A. Yes, I did.

20 Q. And where was that?

21 A. It was -- at the time it was called  
22 Evanston Continent Center here in Evanston,  
23 Illinois, under Northwestern University, and now we  
24 are called NorthShore University HealthSystem.

1 Q. And when was -- when was your fellowship?

2 A. 1995 to 1997.

3 Q. And what did you do after you completed  
4 your fellowship?

5 A. I went into practice.

6 Q. And what was your first job in practice?  
7 Where did you first practice?

8 A. I practiced at Advocate Christ Medical  
9 Center.

10 Q. And how long did you work at Advocate  
11 Christ Medical Center?

12 A. Four-plus years.

13 Q. Okay. And after Advocate Christ Medical  
14 Center, what was your next position?

15 A. I left Advocate to become the director of  
16 urogynecology at Northwestern Memorial Hospital for  
17 the Northwestern Medical Faculty Foundation.

18 Q. Okay. And, Doctor, how long did you hold  
19 that position?

20 A. Approximately nine years.

21 Q. Okay. And after that position, where --  
22 where did you work?

23 A. Then I came to NorthShore University  
24 HealthSystem.

1 Q. Okay. And, Doctor, that's your current  
2 position?

3 A. That's my current position, yes.

4 Q. And what's your current title at  
5 NorthShore University -- NorthShore HealthSystem?

6 A. I am just a specialist in female pelvic  
7 medicine and reconstructive surgery.

8 Q. And, Doctor, do you have any board  
9 certifications?

10 A. Yes, I do.

11 Q. Okay. And what certifications are those?

12 A. I am board certified in obstetrics and  
13 gynecology and in female pelvic medicine and  
14 reconstructive surgery.

15 Q. Doctor, when did you become board  
16 certified in obstetrics and gynecology?

17 A. In -- that's a good question. I have to  
18 look at my CV.

19 Q. Please. Please do.

20 A. All of these years start to blend  
21 together.

22 Immediately, the first year I could become  
23 board certified. So that was November 1 -- I'm  
24 sorry -- yes, November 1998.

1 Q. And, Doctor, you also mentioned you're  
2 board certified in female pelvic medicine and  
3 reconstructive health?

4 A. That's correct.

5 Q. And when did you become board certified in  
6 that?

7 A. 2013, the first year you could become  
8 board certified.

9 Q. And, Doctor, are you licensed in Illinois?

10 A. Yes, I am.

11 Q. And, Doctor, have you performed any  
12 research in your medical career after medical  
13 school?

14 A. Yes, I have.

15 Q. And what's the general nature of that  
16 research?

17 A. I have done different research.

18 I have performed research on medications  
19 for overactive bladder.

20 I have performed surgical research for  
21 vaginal prolapse.

22 And I have done also spinal curvature  
23 research having to do with prolapse occurrence,  
24 research on nonsurgical management of urinary

1 incontinence.

2 Q. And has any of that research been funded  
3 by Johnson & Johnson or Ethicon?

4 A. No, it has not.

5 Q. Have you been involved in any clinical  
6 studies in your medical career?

7 A. Yes, that's under the research.

8 Q. Okay. Were any of those studies specific  
9 to stress urinary incontinence?

10 A. Not addressing just stress urinary  
11 incontinence, but, yes, they did.

12 Q. Okay. Can you explain what you mean by  
13 that?

14 A. One of the studies I was involved in was  
15 nonsurgical management of urinary incontinence,  
16 which included urge and stress urinary  
17 incontinence, and then the prolapse studies also  
18 include and evaluate urinary incontinence as part  
19 of the studies.

20 Q. And when was the clinical study to  
21 evaluate nonsurgical treatments of stress urinary  
22 incontinence?

23 A. So I had -- I participated in -- also  
24 medication studies too -- which was in 2006, 2007,

1 2002, 2004, back to 1999, and then through the  
2 years, the other research studies have been from  
3 '99 on through 2010, 2012.

4 Q. And shifting gears a little bit, Doctor,  
5 do you currently implant the retropubic TVT  
6 product?

7 A. I do retropubic midurethral slings.  
8 Currently, our hospital system does not use TVT  
9 products.

10 Q. And which retropubic midurethral sling  
11 product does your hospital use?

12 A. Right now we use Boston Scientific.

13 Q. Is there a specific product name?

14 A. Oh, I'm sorry. Advantage Fit.

15 Q. Advantage Fit.

16 So, doctor, have you previously implanted  
17 the TVT Retropubic product?

18 A. Yes, I have.

19 Q. And when did you begin implanting the  
20 TVT Retropubic product?

21 A. I think I began around 1999.

22 Q. So around the time it was first  
23 introduced; is that fair?

24 A. That's correct.



1 Q. And when did you cease using the  
2 TVT Retropubic product?

3 A. Our hospital system switched over based on  
4 contracts.

5 Q. Okay. And --

6 A. So I believe that was two or three years  
7 ago. It was not a physician decision.

8 Q. So, Doctor, did you use the TVT Retropubic  
9 product yourself for about 15 years; is that fair?

10 A. Approximately, yes.

11 Q. And how did you come to use it initially  
12 in 1999?

13 A. Can you be more specific with that  
14 question?

15 Q. How were -- how were you introduced to the  
16 TVT Retropubic product the first -- prior to the  
17 first time you used it?

18 A. I -- I believe I first learned about it at  
19 our scientific meetings.

20 Q. When you say "our scientific meetings,"  
21 whose scientific meetings?

22 A. Thank you.

23 Our urogynecology scientific meetings such  
24 as AUGS or SGS, and then I went to specific

1 training for it, and my partner at the time was  
2 also training at the same time.

3 Q. And who was your partner at the time?

4 A. It was Denise Elser.

5 Q. E-l-s-e-r?

6 A. Yes.

7 Q. And, Doctor, you mentioned training of the  
8 retropubic TVT device; is that correct?

9 A. Yes.

10 Q. And was that an Ethicon training?

11 A. I do not recall specifically my first  
12 training. I assume it was, but I underwent  
13 different educational programs, and I'm certain  
14 some portion of it was an Ethicon training program.

15 Q. Okay. Well, specific to the training  
16 program you would have attended before you started  
17 using the TVT Retropubic device, you don't remember  
18 if that was Ethicon or not?

19 A. I do not remember when or where it was.  
20 I'm sure I did attend an Ethicon training at some  
21 point, yes.

22 Q. Okay. But prior to using the TVT  
23 Retropubic device for the first time --

24 A. Prior to using it for the first time, yes.

1 Q. -- you are certain you attended an Ethicon  
2 training? You are certain --

3 A. I am certain.

4 Q. Okay, and, Doctor, in the 15 years you've  
5 used the retropubic -- I'm sorry. Strike that.

6 In the 15 years you did use the  
7 TVT Retropubic device, approximately how many have  
8 you implanted in patients?

9 A. I think approximately 1,000 to 1,500.

10 Q. And, Doctor, the retropubic TVT device has  
11 been available in both a laser cut and a mechanical  
12 cut variation; is that correct?

13 MR. SNELL: Form as to time.

14 THE WITNESS: Yes.

15 BY MR. JACKSON:

16 Q. Doctor, at the time you've implanted the  
17 TVT Retropubic device beginning in 1999 until  
18 approximately two or three years ago, have you  
19 implanted both the laser cut and the mechanically  
20 cut version of the TVT?

21 A. Yes, I have.

22 Q. And do you know when you are doing a  
23 surgery whether it's mechanical cut or laser cut?

24 A. Previously?

1 Q. Yes.

2 A. At the time I believe our institution  
3 switched over from mechanical cut to laser cut, and  
4 they only stocked one at the time, you know, one  
5 form at the time. So, yes, I did know that we had  
6 switched from mechanical to laser cut.

7 Q. Okay. And do you have an understanding as  
8 to approximately when your institution would have  
9 switched from mechanical cut to laser cut?

10 A. I do not recall exactly, no.

11 Q. Okay. Doctor, just so -- just to make  
12 sure I'm clear, is it your testimony that you  
13 implanted the mechanical cut TVT and then your  
14 institution switched to the laser cut TVT, and you  
15 began implanting the laser cut TVT?

16 A. Correct.

17 Q. Okay. So, Doctor, was there ever a period  
18 of time where you would have been implanting both  
19 the laser cut and the mechanical cut?

20 A. It's possible based on what they had on  
21 the shelves. I don't remember specifically.

22 Q. Okay. Doctor, is it fair to say that when  
23 you put a laser cut mesh next to a mechanical cut  
24 mesh -- and I'm specifically talking about the TVT

1 Retropubic -- that you can tell the difference?

2 A. Inside the package?

3 Q. No, if they are outside the package.

4 A. When -- if you were to remove the sheaths?

5 Q. Sure.

6 A. So that you can see the mesh?

7 Q. Doctor, let me ask a better question.

8 If you're just holding up a mechanical cut  
9 TVT Retropubic and a laser cut TVT Retropubic next  
10 to each other in your hands, can you tell the  
11 difference looking at them?

12 A. I could not tell the difference, no.

13 Q. And that would just be looking at it with  
14 your -- with your naked eye, correct?

15 A. Correct.

16 Q. Okay. Would you need a microscope to tell  
17 the difference; is that correct?

18 MR. SNELL: Form.

19 Go ahead.

20 THE WITNESS: I've never looked at them under a  
21 microscope myself to try to tell a difference. So  
22 I cannot answer that question.

23 BY MR. JACKSON:

24 Q. Okay. Doctor, you testified that you --

1 your best guess is you've implanted approximately  
2 1,000 to 1,500 retropubic TVTs; is that correct?

3 A. Yes.

4 Q. And do you have an understanding of what  
5 the breakdown would be between the mechanical cut  
6 and the laser cut in terms of how many you've  
7 implanted?

8 A. Based on the years, I'd say maybe a  
9 slightly higher proportion of mechanical than laser  
10 cut, just based on the years that they were  
11 produced.

12 Q. And when you say "based on the years they  
13 were produced," I'm just -- I'm just curious how  
14 you are coming up with the answer that you think  
15 you've implanted slightly more mechanically cut  
16 than laser cut.

17 A. Well, being the last several years that we  
18 -- our institution changed brands. So I can count  
19 those. So those were years of my doing slings, and  
20 I believe they switched over 2005-2006. So the  
21 amount of years that I've been using slings  
22 altogether, probably from 1999 to 2006 or so, was  
23 mechanical cut, and then laser cut after that until  
24 our institution switched. So probably it's a

1 little bit more mechanical cut.

2 Q. Okay. And, Doctor, is it your  
3 understanding that even though your institution  
4 switched to the laser cut TVT Retropubic in,  
5 I think you said approximately 2006, is it your  
6 understanding that the mechanically cut TVT  
7 Retropubic was still on the market being sold at  
8 that time?

9 A. At the time, in my discussions, I believe  
10 it was not simple for us to get the mechanical cut,  
11 and that might have just been an institutional, you  
12 know, they like to order one SKU. So I did not  
13 have a lot of discussions about what was on the  
14 market as what was decided was by the institution,  
15 not by the physicians.

16 Q. Okay. But do you have an understanding as  
17 to whether beginning in 2006 when the laser cut  
18 mesh was available, was the mechanically cut TVT  
19 Retropubic also available at that time? Do you  
20 have an understanding?

21 A. I believe it was.

22 Q. Okay. So your understanding is from 2006  
23 onward, Ethicon was selling both the laser cut and  
24 the mechanically cut TVT Retropubic; is that

1 correct?

2 A. No. Initially, I knew that was correct,  
3 but I actually am not sure as of today.

4 Q. So as of today, you're not sure whether  
5 Ethicon was selling both the mechanically cut and  
6 the laser cut TVT Retropubic from 2006 onward?

7 MR. SNELL: Form.

8 THE WITNESS: Correct.

9 BY MR. JACKSON:

10 Q. Okay. Doctor, did any of the documents  
11 you reviewed in connection with your report in this  
12 case inform you as to whether the laser cut TVT  
13 Retropubic and the mechanically cut TVT Retropubic  
14 were both on the market from 2006 onward?

15 A. I don't recollect seeing that in the  
16 volume of documents, but I can't 100 percent say  
17 for sure that it's not there.

18 Q. Okay. Doctor, in 2009, for example, do  
19 you have an understanding of whether both the laser  
20 cut TVT Retropubic and the mechanically cut TVT  
21 Retropubic were being sold by Ethicon?

22 A. I do not.

23 Q. Doctor, other than the retropubic TVT  
24 device, have you ever implanted any other TVT



1 devices yourself?

2 A. I have.

3 Q. Okay. And which -- which devices would  
4 those be?

5 A. I have implanted TVT Secur and only a few  
6 TVT-O.

7 Q. Okay. And do you currently implant the  
8 TVT-O?

9 A. No, I do not.

10 Q. And, Doctor, approximately when would you  
11 have implanted the TVT-O and the TVT-S? Do you  
12 have a sense of that?

13 A. The TVT-O was several years after it was  
14 first on the market, and then I only did a few.  
15 And the same with the TVT Secur, it was probably  
16 two or three years after -- it was not immediately  
17 after it was on the market, and I only did a few.

18 Q. Okay. Doctor, do you currently implant  
19 any Ethicon products at all?

20 A. I will use Prolene suture.

21 Q. In what application?

22 A. In prolapse repair or just in general  
23 suturing wound closure.

24 Q. Okay.

1 A. Our hospital is not an Ethicon hospital.

2 Q. Okay. And, Doctor, just so I'm clear,  
3 when you say "suture," you're talking about an  
4 individual strand of fiber, correct?

5 A. Correct.

6 Q. Okay. And you'd agree with me that a  
7 suture is different from a mesh, correct?

8 MR. SNELL: Form. Vague.

9 THE WITNESS: A suture is a different form, but  
10 it can be of the same material.

11 BY MR. JACKSON:

12 Q. Okay. Doctor, when was the first time you  
13 ever worked with polypropylene mesh of any kind?

14 A. I believe my first use of polypropylene  
15 mesh was with the retropubic TVT.

16 Q. And, Doctor, you've mentioned the  
17 retropubic TVT, the TVT Obturator, the TVT Secur  
18 and the Advantage Fit, correct?

19 A. Yes.

20 Q. Are there any other polypropylene meshes  
21 that you've worked with in your career?

22 A. Yes. I have used Gynemesh for prolapse  
23 repair. I have used other brands of mesh for  
24 sacrocolpopexy also. My Gynemesh would be for

1 sacrocolpopexy also, and I'm sure I have used other  
2 retropubic slings along the way.

3 Q. Doctor, we previously marked as Exhibit 3  
4 the reliance list you provided with your report,  
5 correct?

6 A. Yes.

7 Q. And it's a -- it's a big document,  
8 correct?

9 A. Correct.

10 Q. And have you reviewed every document on  
11 that list?

12 A. I have -- through the years I've seen,  
13 I believe, all of the research, and then the  
14 Ethicon documents I've had access to and have,  
15 I think, briefly reviewed almost every one of them,  
16 yes.

17 Q. Okay. Doctor, as you -- you've mentioned  
18 you reviewed some Ethicon internal documents in  
19 this case, correct?

20 A. Yes.

21 Q. Did you talk to anyone from Ethicon or  
22 counsel for Ethicon about which documents you  
23 should be reviewing?

24 MR. SNELL: Objection. I don't think you are

1 allowed to ask her about my conversations with her.  
2 That's work product, and I don't do that between  
3 Ed and Dr. Rosenzweig and stuff. So I think that's  
4 an improper question as to me.

5 MR. JACKSON: Sure. I can ask a better  
6 question.

7 BY MR. JACKSON:

8 Q. Doctor, how did you -- how did you  
9 determine which Ethicon documents you were  
10 reviewing in connection with your report in this  
11 case?

12 A. I reviewed Ethicon documents that were  
13 included in the medical experts' reports, and  
14 they're in many of the medical expert reports.

15 And then I was also supplied with some  
16 others.

17 Q. Okay. Doctor, how did you first become  
18 involved in this case?

19 A. I was contacted by Butler Snow as an  
20 expert in the area.

21 Q. And, obviously, I'm not asking you to  
22 violate any attorney-client privilege or anything  
23 like that, but can you just describe how you were  
24 contacted by Butler Snow? I mean, did you get a

1 phone call out of the blue?

2 A. The original contact, I believe, was by  
3 e-mail, and I don't -- now I don't remember  
4 actually.

5 Q. Doctor, is it fair to say that someone  
6 from Butler Snow contacted you in about February of  
7 this year to ask if you might be interested in  
8 providing an expert report in this case?

9 A. Yes.

10 Q. Okay. And at that time did you have an  
11 understanding that they wanted you to provide an  
12 opinion that the TVT Retropubic device was safe and  
13 effective?

14 A. It was my understanding that they wanted  
15 me to provide my opinion about the TVT Retropubic  
16 device.

17 Q. But did you have an understanding that  
18 anybody wanted your opinion to be that the TVT  
19 Retropubic device was safe and effective?

20 A. No.

21 MR. SNELL: Objection. Form.

22 Go ahead.

23 THE WITNESS: Sorry.

24 No, it was very clear that they wanted my

1 opinion, no matter what that opinion was.

2 BY MR. JACKSON:

3 Q. Okay. So if you had reached the opinion  
4 that the TVT Retropubic device was not safe and  
5 effective, you still would have submitted a report  
6 on behalf of Ethicon in this case?

7 A. I can't answer that question.

8 Q. Why can't you answer that question?

9 A. Because that was not the situation.  
10 I don't know what would have happened in a  
11 situation that did not occur.

12 Q. Okay. Doctor, when you used the TVT  
13 Retropubic device for approximately 15 years in  
14 your practice, did you believe that the  
15 TVT Retropubic device was safe and effective?

16 A. Yes, I did.

17 Q. And, Doctor, when you were first -- sorry.  
18 Strike that.

19 Doctor, at the time you were first  
20 contacted by Butler Snow in approximately  
21 February of 2016, did you hold the opinion that the  
22 TVT Retropubic device was safe and effective?

23 A. Yes, I do.

24 Q. So, Doctor, at the time you began your

1 work in this case, you already believed that the  
2 TVT device, the TVT Retropubic device was safe and  
3 effective, correct?

4 A. Absolutely.

5 Q. And is it fair to say you haven't come  
6 across anything that's changed your mind?

7 A. That's correct.

8 Q. Did you see anything or learn anything  
9 that gave you concern about the safety and efficacy  
10 of the TVT Retropubic device?

11 A. No, I did not.

12 Q. Doctor, in regards to the report that  
13 we've marked as Exhibit 1, did you type the report  
14 yourself?

15 A. Yes, I did.

16 Q. Okay. And I believe there are 43 pages.  
17 Is that -- does that sound right?

18 A. Yes.

19 Q. And, just generally, was it a situation  
20 where you reviewed documents and worked on the  
21 report as you went along, or you sat down and typed  
22 all 43 pages at once?

23 A. No, I'm a person that gets a portion of  
24 the topic I want to evaluate and then review the

1 most current literature, review, and my also  
2 general knowledge and then type that kind of  
3 section at a time. I'm a one-section-at-a-time  
4 kind of person.

5 Q. So you worked on it section by section?

6 A. Yes. Sorry. Yes.

7 Q. And, Doctor, I think you mentioned when  
8 you were listing some materials you read in  
9 connection with your report that you looked at the  
10 Instructions for Use for the TVT Retropubic device;  
11 is that correct?

12 A. Yes.

13 Q. Okay. And, Doctor, would you agree with  
14 me it is appropriate for a physician that's going  
15 to implant the TVT Retropubic device to look at  
16 those instructions for use before implanting the  
17 device?

18 A. Yes.

19 Q. And is it appropriate for a physician who  
20 is going to implant the TVT Retropubic device to  
21 rely on those instructions for use?

22 A. I would say we don't rely on the  
23 instructions for use because we are trained to do a  
24 procedure and know about a procedure. That is a



1 portion of the information but that is not  
2 something we rely on for our expertise and the  
3 technique or the procedure.

4 Q. Okay. Doctor, the Instructions for Use  
5 for the TVT Retropubic device list known risks that  
6 come with that device, correct?

7 A. Yes.

8 Q. Okay. So as a physician, is it your  
9 testimony that you did not rely on those warnings?

10 A. I know of those risks through my years of  
11 experience with many operations including different  
12 incontinence operations as well as retropubic  
13 slings. So that is not the only source of my  
14 knowledge. So it's a portion of knowledge, but  
15 it's not the only source of my knowledge.

16 Q. Okay. Doctor, you -- Doctor, is it fair  
17 to say that some surgeons who implant the  
18 TVT Retropubic device don't have as much experience  
19 as you do?

20 MR. SNELL: Form.

21 THE WITNESS: I can't answer that. I would  
22 assume there is some surgeons who do less surgery  
23 than I do.

24

1 BY MR. JACKSON:

2 Q. Doctor, when you started implanting the  
3 TVT Retropubic device in 1999, you had limited  
4 experience implanting devices as a surgeon; is that  
5 correct?

6 MR. SNELL: Object. Form.

7 THE WITNESS: At that time in my career, I had  
8 extensive experience in all different continence  
9 operations, including the most similar pubovaginal  
10 sling. So I did have limited experience in the  
11 TVT Retropubic but extensive experience all around.

12 BY MR. JACKSON:

13 Q. Okay. Doctor, is it the company's  
14 responsibility to warn of the risks that come with  
15 the TVT Retropubic device?

16 MR. SNELL: Form.

17 THE WITNESS: No.

18 BY MR. JACKSON:

19 Q. Why not?

20 A. It's a physician's, as a surgeon's  
21 responsibility to know the risks of procedures.

22 Q. And how does a surgeon learn of the risks  
23 that accompany a given procedure?

24 A. We learn through the literature, through

1 our research, through our meetings. We learn  
2 through our clinical experiences amongst the group,  
3 the AGS, SGS, and the fund of knowledge there is  
4 regarding procedures.

5 Q. So if a company -- strike that.

6 If Ethicon has knowledge of risks that  
7 accompany the TVT Retropubic product, does Ethicon  
8 have an obligation to warn of those risks?

9 MR. SNELL: Form.

10 THE WITNESS: Yes, as a portion of our  
11 knowledge.

12 BY MR. JACKSON:

13 Q. Okay. And one way they might warn about  
14 those risks is through the Instructions for Use; is  
15 that correct?

16 A. Yes.

17 Q. Would you agree that the  
18 Instructions for Use for the TVT Retropubic device  
19 is certainly one way that an implanting surgeon can  
20 learn about warning information that goes with that  
21 device?

22 A. Yes.

23 Q. Certainly not the only way but it's one  
24 way?

1 A. It's one way, yes.

2 Q. Doctor, would you agree that mesh repair  
3 for stress urinary incontinence carries with it  
4 risks that are not present in other surgeries for  
5 stress urinary incontinence?

6 MR. SNELL: Object. Lacks foundation.

7 Go ahead.

8 THE WITNESS: No, I don't.

9 BY MR. JACKSON:

10 Q. The risk of mesh erosion certainly is not  
11 present in nonmesh surgeries, right?

12 A. With each of the incontinent surgeries  
13 that we perform that we implant either suture or a  
14 fascia or a mesh, there is a risk of an exposure or  
15 erosion of that material that we use. So it's just  
16 a matter of which material has that risk, but they  
17 all carry that risk.

18 Q. But it's your testimony that there are no  
19 specific risks that come with the TVT Retropubic  
20 device that are not found in other surgeries?

21 A. When I look at the -- the risk that most  
22 people attribute specifically to mesh, since each  
23 of the surgeries can also have erosions or  
24 rejection of the material, that, to me, all of the

1 surgeries have the same risks, just a matter of  
2 which material, and that's well borne out in the  
3 Level 1 literature where they all have been shown  
4 to have these -- these types of complications.

5 Q. Doctor, the -- just generally, the  
6 TVT Retropubic device is made out of polypropylene  
7 mesh, correct?

8 A. Correct.

9 Q. And polypropylene is a synthetic material,  
10 correct?

11 A. Correct.

12 Q. And the implantation of a synthetic  
13 material could lead to a foreign body response,  
14 correct?

15 A. Every material that we implant leads to a  
16 foreign body response. It does not mean it's a  
17 negative response or a problem. When we operate,  
18 it leads to a response.

19 Q. Doctor, is it your testimony that  
20 implantation of a synthetic material and the  
21 implantation of the patient's native tissue would  
22 result in the same foreign body response?

23 A. That would be different types of responses  
24 for those two different operations.

1 Q. In what way could the responses be  
2 different?

3 A. There is still a response of the body to  
4 the surgery. If you are leaving a material,  
5 whether it's synthetic or autologous or xenograft,  
6 it will have slightly different responses by the  
7 body, but the body still responds to it.

8 Q. Can a -- Doctor, can the implantation of a  
9 polypropylene mesh, such as the TVT Retropubic,  
10 result in a chronic foreign body response?

11 A. I don't believe the literature has borne  
12 out that there is a chronic foreign body response  
13 to the mesh.

14 Q. Doctor, are you aware of any peer-reviewed  
15 literature which suggests that the implantation of  
16 a polypropylene mesh can result in a chronic  
17 foreign body response?

18 MR. SNELL: Object. Form. Overbroad. Scope  
19 as to polypropylene mesh to the extent you are  
20 talking about prolapse, hernia, something beyond  
21 the TVT that she's issued a report on.

22 Go ahead.

23 THE WITNESS: So for the TVT Retropubic sling  
24 mesh, the literature, the Level 1 literature, shows

1 longstanding safety without any chronic problems of  
2 chronic foreign body response, low rates of  
3 complications, erosions, pain, et cetera.

4 BY MR. JACKSON:

5 Q. Doctor, are you aware of any peer-reviewed  
6 literature regarding polypropylene mesh as used in  
7 stress urinary incontinence surgery that can result  
8 in a chronic foreign body response?

9 MR. SNELL: Object. Form. Asked and answered.

10 THE WITNESS: No, the literature -- the peer  
11 review Level 1 literature shows that it's a safe,  
12 efficacious product that's tolerated, and if there  
13 was a chronic foreign body response that was  
14 negative, we should see a much more negative  
15 response.

16 BY MR. JACKSON:

17 Q. Okay. I understand that. Doctor, I think  
18 I'm asking a slightly different question.

19 I'm just asking whether you are aware of  
20 any peer-reviewed literature that suggests there  
21 can be a chronic foreign body response in  
22 connection with the implantation of a polypropylene  
23 mesh for stress urinary incontinence.

24 Do you understand that question?

1 A. I do.

2 Q. Okay.

3 A. And I think I looked at the literature  
4 whether they have proven any chronic foreign body  
5 response, and I have not known of any that have  
6 proven a chronic foreign body response. So maybe  
7 I can't answer whether there is any that suggests a  
8 foreign -- chronic foreign body response.

9 Q. And when you say "proven," what do you  
10 mean by that?

11 A. They -- there is -- through the  
12 literature, the Level 1 evidence showing the  
13 safety, the low risk of complications with the  
14 pain, the erosions that has been looked at and has  
15 not shown a chronic foreign body response.

16 Q. Doctor, would you agree that an erosion is  
17 a known risk of the TVT Retropubic device?

18 A. Yes.

19 Q. Is there a difference between erosion and  
20 extrusion in your mind?

21 A. According to the IUGA Classification,  
22 there is, yes.

23 Q. And what is that difference?

24 A. I can pull up the actual document, and



1     they -- I believe they define erosion as a  
2     separation over the mesh versus extrusion is the  
3     mesh going into a cavity.

4           Q.     Okay. So, fair to say, in practice, there  
5     is a difference?

6           A.     Yes, there is.

7           Q.     Doctor, do you believe the implantation of  
8     a TVT Retropubic can result in chronic  
9     inflammation?

10          MR. SNELL: Objection. Asked and answered.

11          BY MR. JACKSON:

12          Q.     Doctor, I asked about chronic foreign body  
13     response before. I'm just asking about chronic  
14     inflammation now. Do you understand the question?

15          A.     I believe I do.

16                  So I don't believe that the TVT device  
17     will develop into a chronic inflammation that has a  
18     clinical effect.

19          Q.     Okay. Doctor, I'm not asking about a  
20     clinical effect. Let me ask a better question.

21                  Are you aware of any peer-reviewed  
22     literature that suggests that the type of  
23     polypropylene mesh contained in the TVT Retropubic  
24     device can result in chronic inflammation, whether

1 you agree with that or not?

2 A. Again, I look at the literature for what  
3 it proves, not what it suggests. So when you say  
4 am I aware of the "suggests," I really look at the  
5 literature for what is proven, and the literature  
6 does not show any chronic inflammation in the  
7 Level 1 evidence.

8 Q. Are you aware of any literature that  
9 suggests that the type of polypropylene mesh used  
10 in the TVT Retropubic can cause chronic  
11 inflammation? Are you at least aware of that  
12 literature?

13 MR. SNELL: Object to form. Asked and  
14 answered.

15 THE WITNESS: I would guess there is something  
16 out there, and you can show it to me specifically,  
17 if there is something you want me to specifically  
18 look at.

19 BY MR. JACKSON:

20 Q. Okay. Doctor, if there is literature out  
21 there that would show that there is a chronic  
22 inflammation associated with the implantation of  
23 the TVT Retropubic device, is it fair to say you  
24 disagree with that literature?

1 MR. SNELL: Object. Lacks foundation.

2 Go ahead.

3 THE WITNESS: I would disagree with that  
4 literature based on the multiple meta-analysis,  
5 long-term studies showing the low rate of  
6 complications that we actually see such as erosions  
7 or pain. So that's what matters.

8 BY MR. JACKSON:

9 Q. Doctor, is there -- Doctor, in your  
10 practice is there a difference between transient  
11 pain and long-term pain?

12 A. Yes.

13 Q. Okay. And what is that difference?

14 A. I think there are multiple definitions for  
15 both, but transient pain, in general, means  
16 something that is short-lived, might be related to  
17 an event; whereas a long-term pain usually is a  
18 chronic pain, in our practice, maybe over six  
19 months, chronic and persistent.

20 Q. Okay. Doctor, is it fair to say that  
21 transient pain might just be normal pain after an  
22 operation that would resolve?

23 A. Correct. I would call normal pain after  
24 an operation a transient pain, as it resolves.

1 Q. And the fact that a pain might be  
2 long-lasting, you'd call it chronic; is that fair?

3 A. Yes.

4 Q. Okay. Doctor, would you agree that  
5 physicians in your field would use a similar  
6 definition of chronic versus transient pain?

7 A. Yes.

8 Q. Doctor, do you believe there is a  
9 significant difference between transient pain and  
10 chronic pain?

11 MR. SNELL: Object. Form. Vague.

12 THE WITNESS: I think they are different, yes.

13 BY MR. JACKSON:

14 Q. Doctor, you testified that transient pain  
15 might just be normal postoperative pain, correct?

16 A. I'm testifying that normal postoperative  
17 pain that occurs from surgery and resolves would be  
18 a form of transient pain, yes.

19 Q. So, Doctor, would you agree that pain that  
20 resolves and pain that may last longer than six  
21 months are significantly different?

22 MR. SNELL: Object. Form. "Significantly."

23 THE WITNESS: Can you clarify "significantly  
24 different" for me?

1 BY MR. JACKSON:

2 Q. Doctor, in your practice, do you see  
3 patients who present with chronic pain that exists  
4 six months after an operation?

5 A. Do I personally see them?

6 Q. Yes.

7 A. It's very uncommon.

8 Q. And, Doctor, in your practice do you see  
9 patients who have pain immediately after a surgery  
10 that then resolves?

11 A. Yes.

12 Q. Okay. And do you view those as  
13 significantly different in your practice?

14 A. There is so many different definitions of  
15 significantly different. I think that's what I'm  
16 getting hung up on. They are both very bothersome  
17 to a patient. They might be managed identically.  
18 It's just you are getting me on the significantly  
19 different.

20 Q. So it's the word "significant"?

21 A. No, it's the word "different." They are  
22 both bothersome to patients. They both have to be  
23 managed. So maybe clarify your definition of  
24 different.

1 Q. Would you counsel a patient differently if  
2 they had short-term pain after a surgery versus if  
3 they had continuing pain six months after a  
4 surgery?

5 MR. SNELL: Object. Form. Vague.

6 THE WITNESS: I can't answer that because  
7 pain -- we might have the exact same treatment. So  
8 that's hard to answer.

9 BY MR. JACKSON:

10 Q. Okay. Doctor, turning to your report that  
11 we've marked as Exhibit 1, you cite a great deal of  
12 literature in this report, correct?

13 A. Yes.

14 Q. Okay. And can you cite any literature in  
15 your report that tracks chronic, long-term pain?

16 A. Chronic, long-term pain in regards to  
17 what?

18 Q. In regards to stress urinary incontinence  
19 surgery.

20 A. As the result of stress urinary  
21 incontinence surgery?

22 Q. Yes.

23 A. The Cochrane Reviews, the meta-analysis,  
24 they all look at pain as one of the outcomes and

1 the also very low rates of pain. There is  
2 different kinds of pain such as dyspareunia.

3 Q. Well, doctor, I'm specifically asking  
4 about chronic, long-term pain. Is it your  
5 testimony that the Cochrane Reviews specifically  
6 track chronic, long-term pain?

7 A. I believe that is one of the variables.  
8 I know in several of the meta-analyses they look at  
9 pain as -- I can find it for you.

10 Q. Well, no. I'm just asking do you have an  
11 understanding whether chronic, long-term pain is  
12 specifically tracked as an end point in any of the  
13 studies you cite?

14 A. So there is many definitions of pain.  
15 I can pull up one -- I can pull up the studies and  
16 read to you their definition of pain.

17 Q. Well, I'm just asking about chronic,  
18 long-term pain.

19 A. So to clarify, I would have to pull up the  
20 study for their definition of pain.

21 Q. Okay.

22 A. They all track pain, but what is your  
23 definition of chronic, long-term pain?

24 Q. Well, Doctor, I thought you said your

1 definition of chronic, long-term pain was pain that  
2 persisted six months after surgery; is that  
3 correct?

4 A. That's my definition but --

5 Q. Doctor, under your definition, are there  
6 any studies you cite that specifically track  
7 chronic, long-term pain as an end point?

8 A. So they do all track pain, but I would  
9 have to look up the specific definitions for each  
10 one.

11 Q. Okay. So --

12 A. So I can pull them up, if you'd like.

13 Q. Well, I'm just asking if you can name a  
14 study you cite right now.

15 A. So, yes, the meta-analysis in the  
16 Cochrane review, they do look at pain as part of  
17 their review.

18 Q. And do they specifically track chronic,  
19 long-term pain as an end point?

20 I'm just looking for a yes or no on that.

21 A. I can't answer that yes or no without  
22 looking at the study to know their specific  
23 definition of pain.

24 Q. And, Doctor, do you -- do you rely on the



1     Cochrane review to support your opinion in your  
2     report that the TVT Retropubic device is safe and  
3     effective?

4             A.     Yes.

5             Q.     You do.

6                     And is there a specific year of the  
7     Cochrane review that you are relying on?

8             A.     There are several years the Cochrane  
9     review has come out, and the most recent year is  
10    2015.

11            Q.     And sitting here, do you know whether the  
12    2015 Cochrane review specifically uses chronic,  
13    long-term pain as an end point?

14            A.     Again, I have -- I would have to look at  
15    the document to look for pain and the definition of  
16    pain.

17            Q.     But sitting here right now, is it fair to  
18    say you're not sure?

19            A.     Correct. I'm not sure. I'd have to look  
20    at the document.

21            Q.     Doctor, is there a randomized clinical  
22    trial anywhere for polypropylene mesh to treat  
23    stress urinary incontinence that tracks safety as  
24    the primary end point?

1           A.     Most of the studies, the primary  
2     end points are efficacy, and secondary end points  
3     are safety.

4           Q.     So do you know of anywhere that's  
5     reversed, where safety is the primary end point?

6           A.     I do not, off the top of my head, no.

7           Q.     Okay. Doctor, are there any studies that  
8     you believe support your opinion that the  
9     TVT Retropubic device is safe and effective that  
10    specifically track dyspareunia as an end point?

11          A.     As a primary end point or the secondary  
12    end point?

13          Q.     Let's start with the primary end point.

14          A.     Not that I believe for a primary  
15    end point.

16          Q.     And how about as a secondary end point?

17          A.     It's usually tracked as a portion of the  
18    data, but I don't believe they are tracked as a  
19    secondary end point either, as a specific secondary  
20    end point.

21          Q.     So, Doctor, just to be clear, you don't  
22    believe there are any studies that support your  
23    opinion that the TVT Retropubic device is safe and  
24    effective that track dyspareunia as either a

1 primary or secondary end point, correct?

2 A. I'm sorry. I believe you asked me if it  
3 was a randomized controlled trial. I'm sorry.  
4 Maybe I misunderstood.

5 Q. I think I was asking about just any  
6 studies. So let me back up.

7 Are there any studies that you know of  
8 that support your opinion that the TVT Retropubic  
9 device is safe and effective that track dyspareunia  
10 as a primary end point?

11 A. So the primary end points are usually done  
12 in randomized controlled trials.

13 So the meta-analysis and the Cochrane  
14 Reviews are looking at all the points, not just the  
15 primary or secondary end point.

16 So in terms of the best literature,  
17 Level 1 literature, looking at the end points of  
18 dyspareunia or pain, those are the best sources  
19 because they put together the most literature.

20 In a smaller, randomized, controlled  
21 trial, dyspareunia or chronic pain are not usually  
22 a secondary or primary end point because the rate  
23 is so low, you'd need just thousands of patients to  
24 use as a secondary or primary end point.

1           So the best literature to look at is the  
2   meta-analysis and the Cochrane Reviews because they  
3   pull -- they pull all the literature, and then they  
4   can look at those, and at that point they are not  
5   called primary or secondary end points. They are  
6   just part of what they are looking at.

7           Q.    Let me ask a very simple question, and  
8   I think we can move on.

9           Are there any studies that you believe  
10   support your opinion that the TVT Retropubic device  
11   is safe and effective that specifically track  
12   dyspareunia as a primary end point?

13          MR. SNELL: Object to form. Asked and  
14   answered.

15   BY MR. JACKSON:

16          Q.    I'm just looking for a yes or no.

17          A.    So yes.

18          Q.    What studies?

19          A.    I believe, as I just explained, that the  
20   Cochrane Reviews in the meta-analysis that use them  
21   as an end point in their research, that those  
22   studies support that.

23          Q.    Okay. And it's your testimony that the  
24   2015 Cochrane review specifically tracks

1 dyspareunia as a primary end point?

2 A. So, again, not using the word "primary end  
3 point." They don't use primary end point. They  
4 look at categories.

5 Q. Doctor, would you agree with me that one  
6 or more revision surgeries may be necessary to  
7 treat adverse reactions after the implantation of a  
8 TVT Retropubic device?

9 A. Yes.

10 Q. Doctor, do you believe that the entire TVT  
11 Retropubic device can be removed after it's ingrown  
12 into a woman's tissues?

13 A. I believe that you can attempt to remove  
14 the entire device, and I'm not sure, on a  
15 microscopic level, that you can remove the entire  
16 device.

17 Q. Okay. Doctor, have you personally  
18 performed TVT removal surgeries yourself?

19 A. Yes, I have.

20 Q. About how many?

21 A. Do you mean -- can you clarify what kind  
22 of removal?

23 Q. Doctor, have you ever personally removed  
24 an entire TVT device yourself?

1           A.     I have never had a case where I needed to  
2     remove an entire TVT. I've had to remove a large  
3     portion of it.

4           Q.     So fair to say you've never removed an  
5     entire TVT device yourself?

6           A.     Correct. I've never been in a situation  
7     where I've needed to.

8           Q.     Okay. Do you know anybody who has --

9           A.     Yes.

10          Q.     -- removed an entire TVT device yourself?

11          A.     Sorry. Yes, I have.

12          Q.     And who would that be? Do you know?

13          A.     Is that privileged information?

14          Q.     I mean, I'm -- I'm asking for -- do you  
15     know the name of a surgeon who -- who's removed an  
16     entire TVT device?

17          A.     Yes, I do.

18          Q.     Okay. And can you tell me who that is?

19          A.     Wouldn't -- I'm concerned about privileged  
20     information because those are done so rarely that  
21     by naming that physician, it could easily lead to  
22     the patient identification because it's so rare  
23     that it's done, but, yes, I do.

24                 I will tell you one of my partners

1 recently removed one.

2 Q. A partner you currently --

3 A. Work with, yes.

4 Q. -- work with recently removed an entire  
5 TVT Retropubic device?

6 A. Well, I'm sorry. I should clarify that.  
7 I'm not sure she was certain it was a TVT, but it  
8 was a retropubic sling. Sorry. It may not have  
9 been a TVT.

10 Q. Okay. So --

11 A. But for the technique of removing an  
12 entire retropubic sling.

13 Q. And I'm certainly not trying to violate  
14 anyone's privacy or anything, but, Doctor, let me  
15 try to ask a simple question here. Sitting here  
16 today, do you personally know of anyone who has  
17 removed an entire TVT Retropubic device?

18 A. So beyond the records that I have reviewed  
19 where they might have stated that they've removed  
20 an entire device, I know of people who removed --  
21 have removed entire retropubic slings, and I'm just  
22 not sure if they were TVT slings or not.

23 Q. So is it fair to say that sitting here  
24 today, you can't say that you have -- you can't say

1 you know of someone who has removed an entire TVT  
2 Retropubic device; is that fair?

3 A. No, because I do know of people who have  
4 removed them as part of the record, of patient  
5 records as part of the cases.

6 Q. And is that from the literature?

7 A. No, patient cases.

8 Q. Okay. Doctor, would you agree that  
9 removing an entire TVT Retropubic device may  
10 require aggressive dissection?

11 A. Yes, I would.

12 Q. And, Doctor, would you agree that there is  
13 no guarantee a surgeon would be able to remove an  
14 entire TVT device in the event it needed to be  
15 removed?

16 MR. SNELL: Form.

17 THE WITNESS: I agree.

18 BY MR. JACKSON:

19 Q. Doctor, would you agree that -- let me  
20 back up.

21 Doctor, you said you've personally  
22 performed revision surgeries on TVT Retropubic  
23 devices; is that correct?

24 A. I have performed revision surgeries on TVT



1 as well as other retropubic devices.

2 Q. Okay. Have you ever seen any pathology  
3 reports of the TVT Retropubic mesh that you've  
4 personally removed?

5 A. Yes, I have.

6 Q. Okay. Have you ever held the -- I'm  
7 sorry. Strike that.

8 After you've removed portions of a  
9 retropubic TVT device, have you held the mesh in  
10 your hands?

11 A. Yes.

12 Q. Has it ever felt stiff?

13 A. No, it usually feels normal.

14 Q. Okay. Would you agree that the mesh can  
15 be stiff when it's removed?

16 MR. SNELL: Object. Form. Speculation.

17 THE WITNESS: I would not know.

18 BY MR. JACKSON:

19 Q. Doctor, when mesh is removed, is it  
20 possible to just take the mesh out, or do you also  
21 have to take out mesh and surrounding scar tissue?

22 A. It depends on the case.

23 Q. Doctor, have you seen cases where just  
24 TVT Retropubic mesh was removed without any scar

1 tissue also being removed?

2 A. So I'm going to speak to my general  
3 removal of retropubic slings because it's not  
4 always you can say that it's a TVT. So in specific  
5 cases I've had to remove some where it's just the  
6 sling that comes out, and actually very easily, and  
7 sometimes there is surrounding tissue, yes.

8 Q. Doctor, are you able to answer the  
9 question specifically regarding the TVT Retropubic,  
10 though, or can you only speak with your experience  
11 with all -- all midurethral slings?

12 A. I -- I have to speak to my experience with  
13 polypropylene midurethral slings because we don't  
14 always know the original, which sling was  
15 originally implanted.

16 Q. So is it fair to say you may be relying on  
17 experience with other products to inform that  
18 opinion on the TVT Retropubic?

19 A. Yes.

20 Q. Doctor, would you agree that the way to  
21 manage complications that are associated with the  
22 TVT Retropubic device is typically to remove a  
23 portion of the mesh?

24 MR. SNELL: Object. Form.

1 THE WITNESS: You would need to be -- to  
2 clarify for me on what type of complication you're  
3 talking about.

4 BY MR. JACKSON:

5 Q. Doctor, in your practice are there  
6 complications that can arise after the implantation  
7 of the TVT Retropubic device where the way to  
8 manage those complications is to remove a portion  
9 of the device?

10 A. Yes, there are complications that might  
11 occur where it is necessary to revise a portion of  
12 the sling, the TVT device.

13 Q. Okay. And, Doctor, is it fair to say that  
14 a physician, such as yourself, who may be revising  
15 a portion of that sling has to make a judgment  
16 about how much mesh to remove?

17 A. Yes.

18 Q. So it's a judgment call at that point?

19 A. It's based on the clinical scenario.

20 Q. So if a doctor decides to remove only a  
21 portion of the mesh and some mesh is left behind,  
22 you're not here to fault a doctor for making a  
23 judgment about how much mesh to remove?

24 A. Correct.

1 Q. Doctor, would you agree that in many cases  
2 removal of a portion of the mesh does not solve the  
3 complications?

4 MR. SNELL: Form. Lacks foundation.

5 THE WITNESS: You'd have to put it in context.

6 BY MR. JACKSON:

7 Q. Doctor, have you seen patients who have  
8 presented to you with erosions of the TVT device?

9 A. This is where it gets hard for me because  
10 I do see patients who have erosions of retropubic  
11 slings, and, again, oftentimes, they're not  
12 patients that I know which procedure that they had.  
13 So I have to say it's a general polypropylene mesh  
14 retropubic midurethral sling that I can comment on.

15 Q. So you can't speak specifically to the  
16 TVT Retropubic?

17 A. I -- I did not go back and look at my  
18 cases to fortunately where, to see which ones  
19 specifically were TVTs, and then the vast majority  
20 of revision surgery that I have done has come in  
21 from other physicians.

22 Q. Doctor, have you specifically treated  
23 patients for chronic pain associated with  
24 midurethral slings?

1           A.     Can you define what type of chronic pain  
2     do you mean?   Like whole body pain?   Local pain?

3           Q.     Doctor, have you specifically treated any  
4     patients for chronic pain using your definition  
5     that you believe to be a result of a midurethral  
6     sling?

7           A.     I have treated patients for local pain.  
8     So being very specific, it's usually at the sling  
9     site or mid --

10          Q.     That would be chronic pain?

11          A.     Chronic, more than six months' duration,  
12     local pain for retropubic midurethral slings, yes.

13          Q.     And can you say whether you have treated  
14     any patients for chronic, local pain at the  
15     implantation site following a TVT Retropubic  
16     device?

17          A.     I cannot say specifically whether it was  
18     TVT.

19          Q.     Okay.   And, Doctor, you've mentioned you  
20     had to partially remove TVT Retropubic devices,  
21     correct?

22          A.     I can specifically say that revision  
23     surgeries I've had to do on TVT Retropubic devices  
24     were usually just incising a sling for voiding

1 dysfunction. The other sling surgeries where  
2 I might have had to remove a portion, those are the  
3 ones I'm not sure whether they were truly TVTs or  
4 not.

5 Q. Doctor, have you ever personally tested a  
6 TVT Retropubic mesh for degradation?

7 A. No.

8 Q. Okay. Have you ever tested a device of  
9 any kind for degradation?

10 A. No.

11 Q. Has anyone you worked with ever done that?

12 A. Not that I'm aware of.

13 Q. Are you familiar with the chemical process  
14 of oxidative degradation?

15 A. Yes, I am.

16 Q. And how are you familiar with the chemical  
17 process of oxidative degradation?

18 A. Just through the literature regarding  
19 degradation of slings and mesh materials.

20 Q. Do you know what sort of polypropylene is  
21 in the Ethicon mesh --

22 MR. SNELL: Form.

23 BY MR. JACKSON:

24 Q. -- specific to the TVT Retropubic device?

1 MR. SNELL: Form again.

2 THE WITNESS: And by what sort of -- do you  
3 mean the chemical structure, or do you mean --

4 BY MR. JACKSON:

5 Q. Doctor, do you know who manufactures the  
6 polypropylene mesh used in the TVT Retropubic  
7 device?

8 A. It's my belief that it's Ethicon.

9 Q. Doctor, do you know -- back up.

10 Doctor, the polypropylene mesh is woven  
11 out of polypropylene fibers, correct?

12 A. Correct.

13 Q. And the polypropylene fibers are made out  
14 of a polypropylene resin; is that fair?

15 A. Yes.

16 Q. And, Doctor, do you know who manufactures  
17 the polypropylene resin that ends up in the mesh in  
18 the TVT Retropubic device?

19 A. I do not know who -- when it starts at the  
20 petroleum or wherever it starts, I don't know who  
21 manufactures that, no.

22 Q. Doctor, do you know whether or not pure  
23 polypropylene degrades without antioxidants?

24 MR. SNELL: Object. Form as to scope.

1 Overbroad.

2 THE WITNESS: I do not know.

3 BY MR. JACKSON:

4 Q. Doctor, are you aware of any established  
5 science by chemists that shows that pure  
6 polypropylene could degrade without antioxidants?

7 A. No, I don't have knowledge.

8 Q. Doctor, do you know which antioxidants are  
9 added to the polypropylene in the TVT Retropubic  
10 device?

11 A. I do not.

12 Q. Doctor, in connection with the preparation  
13 of your report, have you undertaken an independent  
14 analysis of the antioxidants in the mesh in the  
15 TVT Retropubic device?

16 A. No, I have not.

17 MR. JACKSON: Why don't we go off the record  
18 and take a little break? We have been going a  
19 little over an hour.

20 (Whereupon, a discussion was had  
21 off the written record but on  
22 the video record.)

23 THE VIDEOGRAPHER: The time is 9:29 a.m. This  
24 is the end of Tape 1. We are off the record.



1 (A short break was taken.)

2 THE VIDEOGRAPHER: The time is 9:40 a.m. This  
3 is the beginning of Tape 2, and we are back on the  
4 video record.

5 (Whereupon, TOMEZSKO Exhibit 7  
6 was marked for identification.)

7 BY MR. JACKSON:

8 Q. Doctor, I've premarked an exhibit while we  
9 were off the record, and it's Exhibit 7. And this  
10 is the Instructions for Use of the TVT Retropubic  
11 device, and that is the 2008 version of those  
12 Instructions for Use.

13 Have you seen this document before?

14 A. Yes, I have.

15 Q. Okay. And you'll see, if you turn to the  
16 page on the bottom right corner that ends in 0531,  
17 do you see that page?

18 I believe it's the fourth page.

19 A. Yes, I do.

20 Q. Okay. And under "Contraindications," do  
21 you see that section?

22 A. Yes.

23 Q. It says "As with any suspension surgery,  
24 this procedure should not be performed on pregnant

1 patients. Additionally, because polypropylene mesh  
2 will not stretch significantly, it should not be  
3 performed in patients with future growth potential,  
4 including women with plans for future pregnancy."

5 Do you see that?

6 A. Yes, I do.

7 Q. Doctor, would you agree with me that this  
8 version of the Instructions for Use doesn't list,  
9 as a contraindication, that the TVT Retropubic  
10 device should not be used in obese women?

11 MR. SNELL: Object. The document speaks for  
12 itself.

13 Go ahead.

14 THE WITNESS: Correct.

15 BY MR. JACKSON:

16 Q. And, to your knowledge, does the  
17 TVT Retropubic IFU say anywhere that it should not  
18 be used in women who smoke, for example?

19 A. Correct. It does not say it should not be  
20 used in women who smoke.

21 Q. And it doesn't say anywhere that it should  
22 not be used in women who have weak connective  
23 tissue, for example?

24 A. Correct.

1 Q. And is it fair to assume that Ethicon  
2 would have known that the TVT Retropubic -- I'm  
3 sorry. Strike that.

4 Is it fair to assume that Ethicon would  
5 have known that there is a certain portion of the  
6 population who is obese?

7 A. Yes.

8 Q. And they didn't say that these woman  
9 shouldn't get the device, did they?

10 A. Correct.

11 Q. Is it fair to say that if Ethicon thought  
12 these women should not get the device, they would  
13 have put that in the contraindications?

14 MR. SNELL: Object. Calls for speculation.

15 THE WITNESS: Is it fair to say if they thought  
16 that it was a contraindication, they would have put  
17 it in their -- I would assume so.

18 BY MR. JACKSON:

19 Q. And, Doctor, the TVT Retropubic device is  
20 obviously intended for women with stress urinary  
21 incontinence, right?

22 A. Correct.

23 Q. And is it fair to say that women with  
24 stress urinary incontinence often have other

1 comorbidities?

2 A. Yes.

3 Q. And the TVT Retropubic device, in your  
4 opinion, is perfectly acceptable to implant in  
5 women with stress urinary incontinence despite  
6 their comorbidities?

7 A. So there are many potential comorbidities,  
8 but, yes, the TVT device is safe with most  
9 comorbidities. We'd have to be more specific.

10 Q. Can you give me an example of a  
11 comorbidity that you may see in a patient where you  
12 would choose not to implant the TVT Retropubic  
13 device?

14 A. I may not implant a TVT on someone who is  
15 about to undergo radiation therapy to the vagina.

16 Q. Okay. And why is that?

17 A. Because radiation causes damage to tissues  
18 intentionally.

19 Q. Okay. And is that -- is that common  
20 knowledge for any -- any surgeon?

21 A. Yes.

22 Q. Okay. And, Doctor, if you see the first  
23 bullet point under "Warnings and Precautions" on  
24 this same page, it says "Do not use Gynecare TVT

1 procedure for patients who are on anticoagulation  
2 therapy."

3 Did I read that right?

4 A. Correct.

5 Q. And is it fair to say that certainly you  
6 don't want to implant a TVT Retropubic device for a  
7 patient who is currently on Xarelto, for example?

8 A. That's correct.

9 Q. Because they may start bleeding?

10 A. Correct.

11 Q. And is that common knowledge among  
12 surgeons?

13 A. Yes.

14 Q. Okay. Doctor, are you offering yourself  
15 as an expert with respect to the warnings that come  
16 with the TVT Retropubic device?

17 A. Yes.

18 Q. So do you feel that you're an expert in  
19 what should and what should not be included in the  
20 TVT Retropubic device's warnings?

21 A. Yes.

22 Q. Doctor, let's look at the "Adverse  
23 Reactions" section towards the bottom of this page.

24 The second bullet point says "Transitory

1 local irritation at the wound site and a transitory  
2 foreign body response may occur. These responses  
3 could result in extrusion, erosion, fistula  
4 formation and inflammation."

5 Do you see that?

6 A. Yes.

7 Q. Now, we discussed the definition of  
8 transitory to be what would just be normal  
9 postoperative pain; is that right?

10 A. In regards to pain when we discuss  
11 transitory pain, yes.

12 Q. Okay. And Doctor, under the "Adverse  
13 Reactions" section, there is no mention of  
14 long-term pain, is there?

15 A. In this specific document?

16 Q. Correct, just in the four bullet points  
17 under the "Adverse Reactions" section.

18 A. The print is very small. I have to get my  
19 bifocal contacts just in the right place.

20 Correct. There is no mention of pain.

21 Q. And there is no mention of acute pain, is  
22 there?

23 A. No, I don't believe there is.

24 Q. Okay. And, Doctor, there is no mention of

1 pain with intercourse, is there?

2 A. No, there is not.

3 Q. And, Doctor, do you know with respect to  
4 the TVT Retropubic device's Instructions for Use,  
5 whether there was ever any language that one or  
6 more revision surgeries may be necessary?

7 A. Are you talking about all versions?

8 Q. Correct, yes.

9 Do you have any knowledge of whether there  
10 was ever any language included in the  
11 TVT Retropubic IFU that one or more revision  
12 surgeries may be necessary?

13 A. I'd have to look at the last one again,  
14 but I don't believe it said "one or more revision  
15 surgeries."

16 Q. And, Doctor, do you know if any of the  
17 Instructions for Use for the TVT Retropubic say  
18 that there might be permanent injury to the patient  
19 which may not resolve?

20 A. I would have to look at the wording on the  
21 -- on the most recent one because that's very  
22 vague. It could be any kind of permanent injury.  
23 So I'd have to look at the most recent one.

24 Do you want me to pull that out or --

1 Q. No, just focusing on Exhibit 7 in front of  
2 us, to your knowledge, anywhere in here is there  
3 mention of permanent pain that may not resolve in  
4 connection with the TVT Retropubic TVT device?

5 A. No.

6 Q. Doctor, do you believe Ethicon is  
7 responsible for telling physicians how to properly  
8 tension the TVT device?

9 A. No.

10 Q. And is your answer different if the device  
11 is laser cut versus mechanical cut?

12 A. No.

13 Q. Do you believe the mechanical cut mesh  
14 should be put in with the same amount of tension as  
15 a laser cut mesh?

16 MR. SNELL: Form.

17 Go ahead.

18 THE WITNESS: These are, first of all,  
19 tension-free procedures. So we don't place them on  
20 tension.

21 If you are talking positioning for the  
22 retropubic, I believe the positioning is similar.

23 BY MR. JACKSON:

24 Q. Doctor, specifically with regard to the



1 TVT Retropubic device, do you have an understanding  
2 as to whether Ethicon instructs physicians as to  
3 how to properly tension the device?

4 A. Are you talking about whether they are  
5 currently instructing physicians on how to properly  
6 tension it?

7 Q. Whether they ever have.

8 A. As part of the training, at least  
9 originally, they did discuss ways to tension,  
10 position the mesh.

11 Q. Okay. And, Doctor, specifically with  
12 regard to the TVT Retropubic device, do you believe  
13 the laser cut mesh and the mechanical cut mesh are  
14 tensioned the same?

15 MR. SNELL: Form. Asked and answered.

16 Go ahead.

17 THE WITNESS: I believe they are positioned the  
18 same.

19 BY MR. JACKSON:

20 Q. Do you believe they are tensioned the  
21 same?

22 A. Can you then define tension, if I'm  
23 misunderstanding?

24 Q. Well, what's your definition of tension?

1           A.     So I don't tension the sling. I position  
2     the sling. So intraoperatively, depending on the  
3     case, whether the patient is awake or under general  
4     anesthesia, I have different methods of how  
5     I position the retropubic slings.

6           Q.     Okay. If a medical director at Ethicon  
7     stated that the laser cut mesh and the mechanical  
8     cut mesh needed to be tensioned differently, would  
9     you disagree with that?

10          MR. SNELL: Objection. Misstates. Lacks  
11     foundation.

12          THE WITNESS: I -- I would disagree with that  
13     as based on clinical practice. I've used many  
14     different -- multiple different slings, and  
15     I pretty much placed them for the retropubic method  
16     all the same. Different methods, whether they have  
17     general anesthesia or they are awake.

18     BY MR. JACKSON:

19          Q.     Okay. So, Doctor, you mentioned earlier  
20     from about 1999 to 2006, you implanted the  
21     mechanical cut retropubic TVT device, correct?

22          A.     Yes.

23          Q.     And from that point, 2006 until  
24     approximately two or three years ago, you implanted

1 the laser cut version of the TVT Retropubic,  
2 correct?

3 A. Yes.

4 Q. And did you implant the two versions of  
5 the TVT Retropubic the same?

6 A. Yes.

7 Q. Okay. Did you have any preference between  
8 the mechanical and the laser cut TVT Retropubic?

9 A. I personally did not, no.

10 Q. You personally did not?

11 A. No.

12 Q. Doctor, would you agree that Ethicon --  
13 I'm sorry. Strike that.

14 Doctor, you said that when you implant the  
15 TVT Retropubic device, there is no tension?

16 A. I'm positioning it.

17 Q. And do you position it tension free?

18 A. The goal is to be tension free, yes.

19 Q. And how do you test whether it's tension  
20 free?

21 A. Before and after I place it, I check the  
22 position of the sling mesh by taking an instrument,  
23 hemostat or some type of instrument, and making  
24 sure I can pass it between the urethra and the

1 sling mesh as the sheaths are removed to make sure  
2 there is adequate movement between the two, that  
3 there is a space between the two that is not  
4 pressed up tightly against the urethra.

5 Q. Doctor, do different surgeons have  
6 different ways of testing whether there is tension  
7 in the TVT Retropubic mesh?

8 A. Absolutely.

9 Q. Doctor, is it -- Doctor, does the --  
10 sorry. Strike that.

11 Some women are obviously built  
12 differently, correct?

13 A. Correct.

14 Q. And is variations in female anatomy a  
15 factor you have to take into account in determining  
16 whether the mesh has been placed tension free?

17 MR. SNELL: Form.

18 Go ahead.

19 THE WITNESS: It's -- the variation in anatomy  
20 is more important when actually placing the sling.  
21 In the end it doesn't matter how their anatomy  
22 looks. I want to make sure the placement is not  
23 pressed tightly against the urethra.

24

1 BY MR. JACKSON:

2 Q. Doctor, do you believe that the TVT  
3 Retropubic device can curl and rope under tension?

4 A. I believe that with significant tension,  
5 it can curl or rope.

6 Q. Doctor, if there were Ethicon documents to  
7 the effect that the TVT Retropubic mesh could curl  
8 and rope, would you want to see those documents?

9 MR. SNELL: Object. Foundation.  
10 It assumes she hasn't.

11 THE WITNESS: As a -- just as an implanting  
12 clinician, do you mean, as opposed to an expert?

13 BY MR. JACKSON:

14 Q. Yes.

15 A. As an implanting physician, I -- we know  
16 all materials can change shape with the wrong use.  
17 So it's one of those common knowledge. So I don't  
18 need to see any internal materials to know that  
19 I can -- you know, I can ruin a suture by tying it  
20 wrong. I can ruin an implant by positioning it  
21 wrong. So I don't think it's really necessary to  
22 see them because it's part of the common knowledge  
23 of procedures that you do have to use the device or  
24 position it correctly.

1 Q. Doctor, have you seen any Ethicon  
2 documents that would suggest that the  
3 TVT Retropubic mesh can curl and rope under  
4 tension?

5 A. Yes.

6 Q. But you don't think it's necessary to see  
7 them?

8 A. Correct, because you know that's part of  
9 procedures.

10 Q. Okay. Doctor, have you seen any Ethicon  
11 documents stating that fraying of the mesh in the  
12 TVT Retropubic device is a concern?

13 A. A concern to who?

14 Q. To Ethicon.

15 A. Yes.

16 Q. Have you seen any Ethicon documents where  
17 fraying of the TVT Retropubic mesh was referred to  
18 as a defect by Ethicon?

19 A. I'm not sure whether it was referred as a  
20 defect or not. I would have to look at them again.

21 Q. Okay. Doctor, wouldn't you want to know,  
22 especially in a case where you are offering an  
23 opinion that the TVT device is not defective,  
24 whether or not Ethicon has called its own device

1 defective?

2 A. Yes, I'm just -- I'd be glad to relook at  
3 those. I'm just not sure of the exact terminology.

4 Q. But if Ethicon had referred to the TVT  
5 Retropubic device as defective, that's certainly  
6 information you'd want to review and consider?

7 MR. SNELL: Object. Foundation.

8 If you have something, the witness has said  
9 she'd look at it. I think you should show it to  
10 her. This is improper.

11 THE WITNESS: Right. So in my -- my clinical  
12 opinion is based on the clinical use. My expert  
13 opinion is based on the clinical use of the  
14 product. So that includes the long-term use of the  
15 product, all the studies that show its safety and  
16 efficacy in human beings and how we use it and how  
17 we actually use it. So that's what my expert  
18 opinion is based upon. So whether Ethicon has a  
19 memo of some sort, that wouldn't change my expert  
20 opinion.

21 BY MR. JACKSON:

22 Q. Doctor, you mentioned that your expert  
23 opinion is based on the clinical use of this  
24 product, right?

1 A. Correct.

2 Q. Your expert opinion is also based on your  
3 experience and clinical use with other midurethral  
4 slings, correct?

5 A. Yes.

6 Q. Doctor, if I could ask you to turn, in  
7 Exhibit 7, to the page which the last four numbers  
8 in the bottom right-hand corner are 0532. I think  
9 it's just the next page.

10 A. Yes.

11 Q. And do you see the section entitled  
12 "Actions"?

13 A. Yes.

14 Q. The last sentence of this section says  
15 "The material is not absorbed, nor is it subject to  
16 degradation or weakening by the action of tissue  
17 enzymes."

18 Do you see that sentence?

19 A. Yes.

20 Q. Okay. And is that a true statement?

21 A. According to my review of the literature  
22 it has not been shown to suffer from degradation by  
23 human enzymes, or I guess this is referring to  
24 animal enzymes -- sorry -- animal studies.



1 Q. Doctor, if basic chemical principles  
2 suggest that polypropylene antioxidants degrades,  
3 would that make this last sentence of the "Actions"  
4 section untrue?

5 MR. SNELL: Object. Lacks foundation. It  
6 calls for pure speculation.

7 THE WITNESS: No, it would not make it untrue  
8 because laboratory studies versus actual in vivo  
9 experience, what's happening in the human body can  
10 be two different things.

11 BY MR. JACKSON:

12 Q. If Ethicon had information that the mesh  
13 used in the TVT Retropubic device did degrade,  
14 would that make this sentence untrue?

15 MR. SNELL: Objection. Lacks foundation.  
16 Calls for speculation.

17 THE WITNESS: So this is talking about  
18 degradation regarding specific enzymes. So just a  
19 vague it does degrade? No, it does not make that  
20 untrue. This is talking specifically versus  
21 certain enzymes.

22 BY MR. JACKSON:

23 Q. Doctor, in your review of Ethicon  
24 documents in connection with your report in this

1 case, did you review any studies that Ethicon did  
2 on dogs where they implanted Prolene in those dogs?

3 A. The Prolene sutures or Prolene mesh?

4 Q. Either one.

5 A. Yes, I believe I did.

6 (Whereupon, a discussion was had  
7 off the written record but on  
8 the video record.)

9 BY MR. JACKSON:

10 Q. Doctor, have you read the deposition of  
11 Dr. Thomas Barbolt in connection with your work on  
12 this report?

13 A. I am trying to remember whether I have.  
14 Is that a materials witness or...

15 Q. He was an Ethicon employee.

16 A. Was that the one testifying for the IFUs,  
17 or what would his testimony have been about?

18 Q. Do you remember any specific testimony --  
19 I'm sorry. Strike that.

20 Do you remember reading anything  
21 Dr. Thomas Barbolt would have said about  
22 degradation?

23 A. Right at this moment I don't remember  
24 reading that specific. I might have, but at this

1 moment I would have to see it to refresh my memory.  
2 There were so many.

3 Q. Fair enough.

4 Doctor, you're offering an opinion in this  
5 case that the mesh in the TVT Retropubic device  
6 does not degrade by oxidative degradation, correct?

7 A. I'm offering the opinion it does not  
8 degrade in the human body based on the evidence  
9 that we see, the safety and efficacy and the  
10 excellent results and then the studies that have  
11 tried to prove degradation, like the Clave study  
12 has not actually proven the degradation.

13 Q. Doctor, to your knowledge, have any  
14 Ethicon employees testified under oath that the  
15 mesh does, in fact, degrade in the body?

16 A. I'm not sure.

17 Q. If -- Doctor, if an Ethicon employee had  
18 testified under oath that the mesh did degrade in  
19 the body, would that make the sentence in this  
20 "Actions" section, that "The material is not  
21 absorbed, nor is it subject to degradation or  
22 weakening by the action of tissue enzymes" untrue?

23 MR. SNELL: Object. Lacks foundation. Calls  
24 for speculation.

1 Go ahead.

2 THE WITNESS: Would that be regarding --

3 MR. SNELL: Actually, asked and answered.

4 Go ahead.

5 THE WITNESS: Would that be regarding sling  
6 mesh or any Ethicon mesh?

7 BY MR. JACKSON:

8 Q. The sling mesh in the TVT Retropubic  
9 device.

10 MR. SNELL: Same objections.

11 THE WITNESS: I don't -- I don't know if their  
12 testimony would make something true or not without  
13 seeing it and knowing the basis of their testimony.

14 BY MR. JACKSON:

15 Q. Okay. Doctor, is it fair to say you cite  
16 several studies about the TVT Retropubic mesh in  
17 your report?

18 A. Yes.

19 Q. Okay. And are any of those studies  
20 specific to laser cut mesh?

21 A. Yes.

22 Q. Can you tell me which one or ones are  
23 specific to laser cut mesh?

24 A. In discussing the issue of laser cut mesh?

1 Q. I'm just looking for a specific study on  
2 the TVT Retropubic using laser cut mesh.

3 MR. SNELL: What page are you at?

4 THE WITNESS: 33.

5 MR. SNELL: 33.

6 THE WITNESS: Yeah.

7 BY MR. JACKSON:

8 Q. Doctor, is there a specific study on  
9 page 33 regarding the TVT retropubic laser cut  
10 mesh?

11 A. I have to refresh my memory. Sorry.  
12 Most of it is talking about the mechanical  
13 cut. So are you talking a study of mechanical cut  
14 versus laser cut?

15 Q. Doctor, do you --

16 A. Because that's -- I don't have that  
17 specifically.

18 Q. So, Doctor, is it your testimony that you  
19 do not reference a specific study on the  
20 TVT Retropubic device that looks at laser cut  
21 versus mechanical cut mesh?

22 A. For the TVT device specifically, correct.

23 Q. Yes.

24 A. At this -- at this moment I would have to

1 look for that, but I don't believe I reference  
2 that, no.

3 Q. Doctor, could you turn to page 34 of your  
4 report, which we've marked as Exhibit 1.

5 A. Yes.

6 Q. And I'm looking towards the top of the  
7 page, a sentence that says "I have not seen a  
8 difference when using mechanically versus laser cut  
9 mesh in complication rates in the literature."

10 Did I read that correctly?

11 A. Correct.

12 Q. What literature have you looked at which  
13 looks at complication rates of mechanically cut  
14 versus laser cut mesh?

15 A. So that's basically based on time frame of  
16 studies. The earlier studies, TVT are done with  
17 mechanical cut, and then later studies are done  
18 with laser cut. So specifically -- so it's -- in  
19 looking at the different versions of the sling,  
20 there has been no specific difference that I'm  
21 aware of.

22 Q. Okay.

23 A. And looking at the larger studies also,  
24 there has been no change in the erosion rate or

1 complication rate after the change where most,  
2 I think, institutions probably changed from  
3 mechanical to laser cut, started using the TVT  
4 EXACT, et cetera.

5 Q. Doctor, are you just making assumptions  
6 about when other institutions made the switch from  
7 laser cut and mechanical cut mesh based on your own  
8 institution?

9 A. No, it just was the availability. So  
10 especially when people changed to the TVT EXACT,  
11 that's laser cut only.

12 Q. Doctor, you mentioned that later studies  
13 only used laser cut mesh, correct?

14 A. So they included laser cut mesh. So  
15 I have to look at each study that you would like to  
16 review and be able to tell you from that.

17 Q. Okay. But, Doctor, sitting here today,  
18 can you identify a single study on the  
19 TVT Retropubic device that only focuses on laser  
20 cut mesh and not mechanical cut mesh?

21 A. It would be TVT EXACT studies, and I do  
22 have some with me. I'd have to find them, pull  
23 them out.

24 Q. You'd certainly agree that the TVT EXACT

1 is a different product than the TVT Retropubic?

2 MR. SNELL: Objection. Lacks foundation.

3 THE WITNESS: I do not agree it is different at  
4 all, and it's a -- it just is a thinner needle.

5 That's it. Laser cut and thinner needle, so  
6 clinically, it's not a different product.

7 BY MR. JACKSON:

8 Q. Doctor, when was the TVT EXACT introduced  
9 into the market?

10 A. I believe it was around 2009. I don't  
11 remember exactly. 2009. 2008 to 2010.

12 Q. And, Doctor, is it your opinion that data  
13 on the TVT EXACT, which was introduced in 2009 or  
14 2010, can support the safety and efficacy of the  
15 TVT Retropubic device with laser cut mesh?

16 A. Yes.

17 Q. And the TVT Retropubic device with  
18 laser cut mesh was on the market for multiple years  
19 prior to the introduction of the TVT EXACT device,  
20 correct?

21 A. Yes, that's my understanding.

22 Q. Doctor, are you familiar with a  
23 Dr. Carl Gustaf Nillson?

24 A. In -- familiar in what respect?



1 Q. Are you aware that Carl Gustaf Nillson was  
2 a co-inventor of the TVT Retropubic device?

3 MR. SNELL: Hold on. Object to foundation.

4 Did you say co-inventor?

5 THE WITNESS: Co-inventor, yes.

6 MR. JACKSON: I did.

7 MR. SNELL: I'm going to have to object on  
8 foundation on that.

9 THE WITNESS: It was my understanding he was a  
10 co-investigator.

11 BY MR. JACKSON:

12 Q. Okay. Doctor, have you heard of  
13 Carl Gustaf Nillson in connection with the  
14 TVT Retropubic device?

15 A. Yes.

16 Q. And whether he was a co-investigator or  
17 co-inventor, are you aware that he had involvement  
18 in the development of the TVT Retropubic device?

19 A. I'm definitely aware he was an  
20 investigator. So into that -- to that, yes.

21 Q. Doctor, have you read any Ethicon  
22 documents where Dr. Nillson offered any opinions  
23 about laser cut mesh?

24 A. I saw some Ethicon e-mails about laser cut

1 mesh, and I'm -- but I'm not sure if that was with  
2 him or not.

3 Q. Have you read any Ethicon documents where  
4 Dr. Nillson expressed an opinion that he would  
5 personally not use laser cut mesh because he  
6 thought it was too stiff?

7 A. I believe I did see e-mails or something  
8 to that effect, but I would have to review them  
9 again.

10 Q. And do you think it's important to know  
11 what Dr. Nillson thinks specifically in regards to  
12 the TVT Retropubic device?

13 MR. SNELL: Form. Vague. Scope.

14 THE WITNESS: I think -- I don't think it's  
15 important in regards to a laser cut versus  
16 mechanical cut because of the persistent success  
17 and longevity of the use, the long-term success of  
18 the procedures being mechanical or laser cut that  
19 continue to occur. So I think the literature,  
20 Level 1 evidence versus the less than Level 5  
21 opinion of his opinion, that's just his own  
22 personal opinion. The Level 1 evidence of the  
23 long-term safety and minimal problems make me  
24 confident in the laser versus mechanical cut.

1 BY MR. JACKSON:

2 Q. Have you -- Doctor, have you seen any  
3 Ethicon documents that suggest that fraying of the  
4 mesh can result in particle loss?

5 A. Yes.

6 Q. And have you seen any Ethicon documents  
7 that suggest that that particle loss can result in  
8 pain?

9 A. I believe they were discussing whether it  
10 could result in pain or not.

11 Q. Would whether particle loss can result in  
12 pain, is that important for you to know as the  
13 physician?

14 MR. SNELL: Object to form. Lacks foundation.

15 THE WITNESS: Again, I think the long -- the  
16 longstanding literature showing such a low pain  
17 rate, less than 2 percent, is really what is more  
18 important. So whether there is particle loss or  
19 not, whatever it's been shown to have such a low  
20 pain rate and dyspareunia rate, that the clinical  
21 experience does not substantiate that as a concern.

22 BY MR. JACKSON:

23 Q. Doctor, are you aware that particle loss  
24 was a reason why Ethicon wanted to use laser cut

1 mesh rather than mechanical cut mesh?

2 MR. SNELL: Object to foundation as to Ethicon.

3 Go ahead.

4 THE WITNESS: I do believe that was part of the  
5 reason.

6 BY MR. JACKSON:

7 Q. Doctor, do you know whether Ethicon did  
8 any studies themselves to see if there were  
9 increased complications due to particle loss?

10 A. Just specifically due to particle loss?

11 Q. Yes.

12 A. I believe there was information regarding  
13 particle loss, but I'm not sure of the extent of  
14 the studies, how the studies were run -- I'm  
15 sorry -- off the top of my head.

16 Q. Doctor, to your knowledge, has Ethicon  
17 done any studies to see if there was any clinical  
18 significance to degradation?

19 MR. SNELL: Objection. Form. Lacks  
20 foundation.

21 The witness has testified there is no  
22 degradation in her opinion.

23 THE WITNESS: So I -- are you talking about  
24 patient studies? Animal studies? What type of

1 studies?

2 BY MR. JACKSON:

3 Q. Has Ethicon done any studies, whether  
4 patient or animal, to your knowledge, to determine  
5 whether or not there is any clinical significance  
6 to any degradation?

7 MR. SNELL: Objection. Lacks foundation as to  
8 there being degradation.

9 Go ahead.

10 THE WITNESS: Yes, I believe they have done  
11 studies.

12 BY MR. JACKSON:

13 Q. And which studies are those?

14 A. So I believe there has been studies on the  
15 Prolene sutures. I believe there has been animal  
16 studies, dog studies.

17 Q. To your knowledge, has Ethicon done any  
18 studies to see whether or not there was any  
19 clinical significance to roping or fraying of the  
20 TVT Retropubic mesh?

21 MR. SNELL: Object. Lacks foundation.

22 THE WITNESS: You said were there any "clinical  
23 studies." So involving patients?

24

1 BY MR. JACKSON:

2 Q. Do you know of any clinical studies?

3 A. I don't believe there were clinical  
4 studies within patients. I believe there were  
5 studies just based on bench research on the mesh  
6 themselves, the slings themselves, specifically  
7 performed by Ethicon that I'm aware of.

8 Q. And, Doctor, how do you determine clinical  
9 significance from a bench study?

10 A. You can't -- in my view you can't  
11 determine true clinical significance just from a  
12 bench study.

13 So you had asked me if there were any  
14 clinical studies.

15 Q. And then you identified some bench  
16 studies, right?

17 A. So I'm not aware of -- so I asked you  
18 specifically if you're asking for studies in  
19 patients, and then you said "any studies."

20 MR. JACKSON: Excuse me just a minute.

21 Why don't we go ahead and mark this as  
22 Exhibit 8, I believe.

23

24

1 (Whereupon, TOMEZSKO Exhibit 8  
2 was marked for identification.)

3 BY MR. JACKSON:

4 Q. And, Doctor, do you see the subject of  
5 this 2012 e-mail is "TVT for Dr. Tomezsko"?

6 A. Uh-huh.

7 Q. And does that refer to you?

8 A. Yes.

9 Q. Who is Michael Trester?

10 A. He was an Ethicon rep. I'm not sure if he  
11 still is.

12 Q. Was he an Ethicon rep that you worked  
13 with?

14 A. Or -- or a Gynecare rep. I'm sorry. I'm  
15 using the wrong terminology.

16 Yes.

17 Q. But he's someone you knew professionally?

18 A. Yes.

19 Q. And who is Dorothy Kase?

20 A. She is an OR person in our  
21 NorthShore University HealthSystem, one of the OR  
22 staff that is involved in purchasing.

23 Q. And, Doctor, do you see where it says  
24 "Dr. Tomezsko said she would prefer the laser cut

1 mesh, which is Product Code 810041BL"?

2 A. Yes, I believe that was for the TVT EXACT.

3 Q. Okay. Do you see anything on this  
4 document to indicate that it was the TVT EXACT?

5 MR. SNELL: Object. Foundation.

6 She didn't write this.

7 THE WITNESS: But my recollection at the time  
8 was trend was converting from the classic to the  
9 EXACT.

10 BY MR. JACKSON:

11 Q. So, Doctor, your testimony is that you  
12 believe this refers to laser cut mesh for the  
13 TVT EXACT?

14 A. I believe so, yes.

15 Q. And, Doctor, is it your understanding that  
16 this -- Doctor, I'm sorry.

17 It says "The hospital is currently  
18 ordering Code 810041B, which is the mechanical cut  
19 mesh."

20 Did I read that correctly?

21 A. Yes.

22 Q. And which product do you believe that  
23 refers to mechanical cut mesh for?

24 A. The TVT Classic, as I wrote down,



1 I believe.

2 Q. And here it says "The laser cut mesh which  
3 is Product Code 810041BL," right?

4 A. Correct.

5 MR. JACKSON: Okay. Can we mark this as  
6 Exhibit 8.

7 THE COURT REPORTER: 9.

8 (Whereupon, TOMEZSKO Exhibit 9  
9 was marked for identification.)

10 MR. JACKSON: Or 9, I'm sorry.

11 MR. SNELL: Do you have one for me by chance?

12 MR. JACKSON: Yeah, I do somewhere.

13 Why don't we just go off the record for a  
14 second.

15 THE VIDEOGRAPHER: The time is 10:22 a.m. We  
16 are going off the video record.

17 (Brief interruption.)

18 THE VIDEOGRAPHER: The time is 10:23 a.m., and  
19 we're back on video record.

20 BY MR. JACKSON:

21 Q. Doctor, I've handed you what we marked as  
22 Exhibit 9, which is a document that says "Product  
23 Pointer Gynecare TVT Tension-Free Support for  
24 Incontinence," and this is a June 26, 2006,

1 document; do you see that?

2 A. Yes.

3 Q. And do you see the bold, underlined  
4 portion towards the top, where it says "We will  
5 continue to have both the mechanically cut and  
6 laser cut meshes for sale"?

7 A. Yes.

8 Q. And do you see where it says "Gynecare  
9 TVT 810041BL"?

10 A. Yes.

11 Q. And is that -- is it your understanding  
12 that that represents the product code for the laser  
13 cut TVT Retropubic?

14 A. I would assume so.

15 Q. Okay. And is that the same product code  
16 that is listed on Exhibit 8 for --

17 A. Yes.

18 Q. So looking at this e-mail, is it still  
19 your testimony that that laser cut mesh would be a  
20 TVT EXACT?

21 MR. SNELL: Object. Hold on. Hold on.

22 Object. Asked and answered.

23 THE WITNESS: The only -- to my recollection,  
24 the only change I remember intentionally trying to

1 make was to the TVT EXACT, and we did change to the  
2 TVT EXACT. So I'm not sure -- so to my  
3 recollection, I don't remember specifically asking  
4 for laser cut versus mechanical cut. I do remember  
5 specifically asking for TVT EXACT at some point.

6 BY MR. JACKSON:

7 Q. So, Doctor, just to wrap this up, you  
8 would certainly disagree with the idea that this  
9 suggests you preferred the laser cut TVT to the  
10 mechanical cut TVT; is that fair?

11 MR. SNELL: Form.

12 THE WITNESS: Correct.

13 I believe in terms of changing to the TVT  
14 EXACT, it was for fellow training, it was easier to  
15 train them, less trauma to the patient tissue.  
16 There were several reasons I remember why I wanted  
17 to change to the TVT EXACT. I do not have an  
18 independent recollection of ever having those  
19 conversations otherwise.

20 BY MR. JACKSON:

21 Q. We can set that aside.

22 Doctor, on page 32 of your report -- I'm  
23 sorry.

24 On page 31 of your report, I'm looking at

1 a sentence which begins on the fourth line down  
2 that says "The Prolene TVT is an Amid Type I  
3 macroporous mesh, which is the generally accepted  
4 classification for biomaterials."

5 Do you see that sentence?

6 A. Yes, I do.

7 MR. SNELL: I'm sorry. Counsel, you were on?

8 MR. JACKSON: 31.

9 BY MR. JACKSON:

10 Q. And, Doctor, in your opinion is  
11 macroporous mesh safer than microporous mesh?

12 A. For the indication of a sling?

13 Q. Yes.

14 A. Yes, it is.

15 Q. Doctor, would you agree that in the  
16 context of polypropylene mesh for stress urinary  
17 incontinence surgery, smaller pore or microporous  
18 mesh is less desirable than macroporous mesh for  
19 tissue ingrowth?

20 MR. SNELL: Object. Foundation.

21 THE WITNESS: Yes.

22 BY MR. JACKSON:

23 Q. Doctor, what is the Amid classification  
24 that you cite to here?

1 MR. SNELL: Objection. Vague as to "here."

2 THE WITNESS: The Amid classification is a  
3 classification by Dr. Amid. He classifies the  
4 different mesh materials from microporous to --  
5 well, from macroporous to microporous from Type I  
6 to Type IV and looking at the pore size and member  
7 weave to basically identify the different mesh  
8 types.

9 BY MR. JACKSON:

10 Q. Doctor, do you have an understanding of  
11 when Dr. Amid came out with that classification?

12 A. I do have his paper with me. I can look  
13 that up, the exact year.

14 MR. SNELL: Would you like her to look that up?

15 MR. JACKSON: No.

16 BY MR. JACKSON:

17 Q. Do you have a general understanding of  
18 when that would have been?

19 A. I believe it was in the '90s, but  
20 I definitely could be wrong about that because I'm  
21 bad with dates, but I would be glad to look it up  
22 for you.

23 Q. Would it be fair to say that Amid's  
24 classification was published prior to the -- prior

1 to the introduction of the TVT Retropubic device?

2 A. I would have to look that up to see.

3 I'm sorry.

4 Q. The TVT Retropubic device was first  
5 marketed in 1999, is that --

6 A. Correct.

7 MR. SNELL: Foundation. Objection.

8 Go ahead.

9 BY MR. JACKSON:

10 Q. What is your understanding of when the  
11 TVT Retropubic device was first marketed in the  
12 United States?

13 A. 1999, I believe, yeah.

14 Q. And is it your understanding that the  
15 Amid pore size classification was developed prior  
16 to 1999?

17 A. I'm sorry. I would have -- I actually  
18 have to look that up to make sure.

19 Q. So sitting here today, you are not  
20 certain?

21 A. At this moment, just with all of this  
22 information, I'm -- to be completely accurate,  
23 I would have to look it up.

24 Q. And --

1 A. Sorry.

2 Q. Is it your understanding that the  
3 Amid classification was developed for mesh and  
4 hernia applications?

5 A. I do believe that's correct. It is for  
6 mesh used throughout the body, but I do believe it  
7 was for hernia applications originally.

8 Q. Doctor, what is your -- I'm sorry. Strike  
9 that.

10 Doctor, what support do you have for the  
11 statement that the Prolene TVT is a Type I  
12 macroporous mesh?

13 A. By his classification, which is pores are  
14 greater than 75 microns, it's usually -- it's a  
15 monofilament with a macroporous of, like, 1.1 to  
16 1.3. So it's over the 75 microns.

17 Q. And the measurements you just gave me,  
18 1.1 to 1.3, where does that come from?

19 A. It -- it comes from -- so basically, I've  
20 looked at it myself, as you can see through -- but  
21 I think throughout many studies, they put down the  
22 size, the Moalli studies, they put down the size of  
23 the pores. So probably the Moalli studies are a  
24 very good source.

1 Q. And, Doctor, do you believe you've done  
2 enough diligence to offer the opinion that the  
3 TVT Retropubic mesh is macroporous?

4 A. Yes, I do.

5 MR. JACKSON: Why don't we mark this as  
6 Exhibit 10.

7 (Whereupon, TOMEZSKO Exhibit 10  
8 was marked for identification.)

9 BY MR. JACKSON:

10 Q. And, Doctor, I'll represent to you that  
11 this is a -- this exhibit is from Ethicon, and do  
12 you see where Ethicon refers to the TVT sling mesh  
13 as microporous?

14 MR. SNELL: Object. Foundation as to Ethicon.  
15 This is not an Ethicon -- the way you stated it,  
16 you lacked foundation. I'll just leave it at that.

17 THE WITNESS: So in this classification they  
18 wrote down "microporous," but there is no -- they  
19 do not have their definition. This is not by  
20 Amid classification. So you need to see their  
21 definition of sizes.

22 BY MR. JACKSON:

23 Q. Doctor, if I suggested that this document  
24 suggests that the Prolene is microporous, you'd



1 disagree with that?

2 MR. SNELL: Form.

3 THE WITNESS: By the standard accepted medical  
4 classification of Amid, it is macroporous. Someone  
5 certainly could have made up their own  
6 classification system and called it microporous,  
7 but the standard that we go by is Amid, and it's a  
8 macroporous mesh.

9 BY MR. JACKSON:

10 Q. Doctor, did you mention that you've  
11 measured the pore sizes on the Ethicon mesh in the  
12 TVT Retropubic device yourself?

13 A. Yes. It would be -- the mesh itself is  
14 see-through, and we show our fellows all the time  
15 with a little ruler to see a millimeter.

16 Q. So that's something you've done --

17 A. Yes, we did.

18 Q. -- just with the naked eye yourself?

19 A. Yes, it's part of teaching.

20 Q. You do that with a ruler?

21 A. Yes.

22 Q. Did you use any microscopic instruments or  
23 anything?

24 A. No, we're just talking about the main, the

1 larger holes in the mesh, yeah.

2 Q. And so your visual examination would be  
3 based on holding a ruler up to the pores of the  
4 mesh?

5 A. Correct. It's not microscopic. Right.

6 Q. And how many times have you done that?

7 A. I don't know altogether. Several -- we  
8 teach fellows and residents, new fellow every year.

9 Q. But your best guess of how many times  
10 you've measured those pores?

11 A. Maybe ten.

12 Q. Doctor, turning back to page 31 of your  
13 report, I'm looking at a sentence just a little  
14 lower than we were before, that says "It is often  
15 described as large pore, lightweight mesh  
16 (AUGS/SUFU 2014 Position Statement)."

17 Do you see that sentence?

18 A. Yes, I do.

19 Q. Doctor, does the AUGS/SUFU 2014 Position  
20 Statement specifically deal with TVT Retropubic  
21 mesh?

22 A. It deals with midurethral slings in  
23 general.

24 Q. Right. But it does not deal with -- I'm

1       sorry. Strike that.

2               It does not deal specifically with  
3       TVT Retropubic devices, does it?

4               MR. SNELL: Objection. Misstates.

5               THE WITNESS: So this -- this sentence is  
6       describing Type I meshes, and this is relating to  
7       Type I meshes in specific. So this sentence of my  
8       report is regarding Type I meshes in specific, and  
9       then also it refers to the Prolene TVT is an  
10      Amid Type I, and then it goes into more specifics  
11      about the Type I meshes. So the AUGS/SUFU report  
12      is talking about Type I meshes in the future.

13      BY MR. JACKSON:

14              Q. And the AUGS/SUFU 2014 Position Statement  
15      looks at the TVT Retropubic device as well as other  
16      devices from other manufacturers, correct?

17              A. Correct, because there have been Type III  
18      meshes that were used, and so they are specifically  
19      supporting the Type I meshes.

20              Q. And when the AUGS/SUFU 2014 Position  
21      Statement discusses Type I mesh, they're referring  
22      to products such as the SPARC mesh, perhaps?

23              MR. SNELL: Objection. Form.

24              Why don't you pull it out, Counsel, or show it

1 to her?

2 BY MR. JACKSON:

3 Q. Is it your understanding that the AUGS  
4 2014 SUFU Position Statement incorporates data from  
5 other products?

6 A. Yes.

7 Q. Doctor, do you recall reading  
8 Brigitte Hellhammer's deposition testimony in  
9 connection with your report in this case?

10 A. Can you remind me what the testimony was  
11 about?

12 Q. I'm just asking if you recall reading a  
13 deposition by somebody with the last name of  
14 Hellhammer.

15 A. I'm bad with names. I remember the  
16 content better than the names. I'm sorry.

17 Q. Do you remember reading deposition  
18 testimony --

19 A. I get called out --

20 Q. -- of a Ms. Brigitte Hellhammer in regard  
21 to pore size of Ethicon'S retropubic TVT meshes?

22 A. I believe I did review that.

23 Q. Do you recall anything she said about the  
24 pore size of the TVT Retropubic mesh?

1 A. Can you be more specific?

2 Q. Are you aware that she testified that the  
3 TVT Retropubic mesh was microporous in her view?

4 MR. SNELL: Object. Lacks foundation.

5 I believe that misstates the actual testimony of  
6 the witness.

7 But go ahead.

8 THE WITNESS: I would have to look at that  
9 context again. I'm sorry.

10 BY MR. JACKSON:

11 Q. Doctor, at the time that Ethicon began  
12 selling the TVT Retropubic mesh in the  
13 United States, do you know whether or not Ethicon  
14 had available to it a lighter weight, larger pore  
15 mesh?

16 A. At that time specifically, I -- I'm not  
17 sure whether they had already developed a lighter  
18 weight, larger pore mesh that they had tested at  
19 all in clinical applications. I'm not sure.

20 For sling application, I mean,  
21 specifically.

22 Q. And, Doctor --

23 A. I know it had to be in -- in process for  
24 applications, though.

1 Q. Okay. Thank you.

2 And you said you don't know whether there  
3 was a lighter weight, lighter pore mesh that had  
4 been tested in clinical applications at the time  
5 the TVT was launched, correct?

6 MR. SNELL: Object. She said "TVT  
7 application."

8 THE WITNESS: So for TVT application, I'm not  
9 sure if there had been any clinical use by Ethicon  
10 at that point. I don't believe there was.

11 BY MR. JACKSON:

12 Q. Would you agree with me, Doctor, that less  
13 synthetic material inside the body is preferable?

14 MR. SNELL: Objection. Overbroad. Lacks  
15 foundation.

16 THE WITNESS: Yeah, I -- I -- can you rephrase?  
17 It's very vague.

18 BY MR. JACKSON:

19 Q. Doctor, when it comes to polypropylene  
20 material in the context of treating stress urinary  
21 incontinence, would you agree with the statement  
22 that less material is better?

23 MR. SNELL: Same objection.

24 Go ahead.

1           THE WITNESS: I do not agree with that because  
2     the study -- remember the name --- the study that  
3     compared the Vypro, the thinner meshes for a sling,  
4     not compared directly to TVT, they had a higher  
5     rejection rate, 4 percent. So I'm not necessarily  
6     sure that a lighter weight, larger pore would be as  
7     effective for the treatment of stress urinary  
8     incontinence if used as a sling. I think that  
9     would need to be borne out in more studies.

10           But the current -- there is one study that  
11     looks at the three slings -- the Vypresh -- the  
12     Vypro, ULTRAPRO, I think it was, and  
13     Vigenis (phonetic), and has been looked at, and it  
14     did not show as good equivalence as the  
15     TVT Retropubic.  
16     I don't think that's been proven yet.

17     BY MR. JACKSON:

18           Q. Doctor, have you seen any Ethicon  
19     documents that indicate that less mesh overall was  
20     preferred?

21           MR. SNELL: Object. Vague. Lacks foundation.

22           THE WITNESS: For what indication?

23     BY MR. JACKSON:

24           Q. For treating stress urinary incontinence.

1           A.     So in terms of Ethicon's opinion, I -- I'm  
2     not sure, but what matters to me more is what  
3     research we have, and what little research we have  
4     on that did not show an improvement in outcome. It  
5     actually showed worse outcome.

6           Q.     Doctor, throughout your report in this  
7     case, you cite a number of complication rates based  
8     on literature, correct?

9           A.     Correct.

10          Q.     And --

11          MR. SNELL: Counsel, if we are going to  
12     transition into something else, can I take a break  
13     and use the restroom real quick?

14          MR. JACKSON: Sure. Let's go off the record.

15          Let's take a break.

16          THE VIDEOGRAPHER: The time is 10:42 a.m., and  
17     we are going off the video record.

18                                 (A short break was taken.)

19          THE VIDEOGRAPHER: The time is 10:52 a.m., and  
20     we are back on the video record.

21     BY MR. JACKSON:

22          Q.     Doctor, before we just went off the  
23     record, I was asking whether you cite complication  
24     rates in your report based on literature.



1 A. Yes, I do.

2 Q. Okay. And the numbers for a given  
3 complication are not uniform, are they?

4 Let me ask a better question.

5 I apologize.

6 Doctor, you cite literature for  
7 complication rates for erosion in your report,  
8 correct?

9 A. Correct.

10 Q. And the erosion rate numbers for the  
11 TVT Retropubic device are not uniform from  
12 publication to publication, are they?

13 MR. SNELL: Object. Form.

14 THE WITNESS: They -- they can vary from  
15 publication to publication, yes.

16 BY MR. JACKSON:

17 Q. Okay. And why do they vary, in your  
18 opinion?

19 A. Well, I believe there is minimal variation  
20 overall. So when you look at the largest -- all  
21 the larger studies, all the meta-analysis, all the  
22 Cochrane Reviews, the reviews, even amongst the  
23 randomized controlled trials, they are fairly  
24 consistent at a 2 percent erosion rate. There is a

1     few outlier studies, and it's hard to explain why  
2     they vary, different definitions, usually, of an  
3     erosion. They may not be all consistent with their  
4     definitions, but when you look at the vast majority  
5     of the literature, the large basis of the  
6     literature, it's all fairly consistent about  
7     2 percent.

8           Q.     I take it you would disagree with me if  
9     I said the erosion rates in the literature vary  
10    significantly?

11          A.     So I would disagree based on the larger  
12    studies, yes.

13          Q.     Okay. And, Doctor, you cite to the  
14    2015 Cochrane review in your report, correct?

15          A.     Correct.

16          Q.     And that's a meta-analysis, correct?

17          A.     Correct.

18          Q.     And I believe you referred to that before  
19    as a Type I evidence, correct?

20          A.     Correct.

21          Q.     And why is a meta-analysis Type I  
22    evidence?

23          A.     It's usually Type I evidence because it  
24    includes the randomized controlled trials.

1 Q. And, Doctor, you believe that the  
2 2015 Cochrane review supports your opinion that the  
3 TVT Retropubic device is safe and effective,  
4 correct?

5 A. Yes.

6 Q. Okay. And I believe we stated earlier  
7 that the Cochrane review -- I'm sorry. Strike  
8 that.

9 The Cochrane review is a meta-analysis of  
10 different studies, correct?

11 A. Yes, it is.

12 Q. Okay. And those different studies --  
13 I'm sorry. Strike that.

14 The Cochrane review that you cite in your  
15 report that cites to different studies and looks at  
16 different studies includes various midurethral  
17 slings, correct?

18 A. That is correct. It does include varied  
19 midurethral slings, but it's heavily weighted upon  
20 the TVT data. The vast majority of the data that's  
21 used is the TVT Retropubic.

22 Q. Okay. And there is also data from other  
23 devices from other manufacturers in the  
24 2015 Cochrane review that you rely on, correct?

1 A. Yes, there is.

2 Q. And so, for example, are you relying on  
3 data on the SPARC and other midurethral slings to  
4 support your opinion that the TVT Retropubic device  
5 is safe and effective?

6 A. Well, since I'm relying on data from  
7 multiple different studies, not just the Cochrane  
8 review, that is part of the Cochrane review but,  
9 again, the vast percentage of all the literature  
10 I'm looking at is TVT Retropubic-based.

11 Q. But would you agree with me you're looking  
12 on -- looking at some literature that relies on the  
13 SPARC, for example, and other midurethral slings to  
14 support your opinion that the TVT Retropubic device  
15 is safe and effective?

16 A. Yes.

17 Q. Okay. So what makes you say the  
18 TVT Retropubic device is safe and effective based  
19 on a different product?

20 MR. SNELL: Object. Form.

21 Go ahead.

22 THE WITNESS: So I'm not doing it based on a  
23 different product, and actually, the Cochrane  
24 review says the retropubic top-down approach, the

1 SPARC, is not included as part of their retropubic.  
2 They're talking about midurethral slings that are  
3 top-up approach. So -- and so the vast majority of  
4 the data -- when you look at the other studies --  
5 the Schimpf, Tommaselli -- they are primarily  
6 TVT Retropubic studies. So I can say with  
7 confidence that this is, you know, this is TVT  
8 Retropubic data primarily.

9 BY MR. JACKSON:

10 Q. And what other top-up products are  
11 included in the 2015 Cochrane review other than the  
12 TVT Retropubic device?

13 A. That's the vast majority. I can --

14 MR. SNELL: Counsel, I think you said top-up  
15 instead of bottom-up --

16 MR. JACKSON: Oh, I'm sorry. Thank you.

17 MR. SNELL: -- unless I misheard.

18 THE WITNESS: He did, but I might have said it  
19 too.

20 BY MR. JACKSON:

21 Q. What other bottom-up slings are included  
22 in the 2015 Cochrane review other than the  
23 TVT Retropubic device?

24 A. Can I look that up for you? Can I --

1 Q. Certainly.

2 A. -- bring it up for you?

3 Do we need to go off the record while I  
4 find it?

5 MR. JACKSON: Sure. Let's go off the record.

6 THE VIDEOGRAPHER: The time is 10:57 a.m., and  
7 we are going off the video record.

8 (Brief interruption.)

9 THE VIDEOGRAPHER: The time is 11:03 a.m., and  
10 we are back on video record.

11 BY MR. JACKSON:

12 Q. Doctor, before we went off the record,  
13 I asked you what other bottom-up slings, other than  
14 the TVT Retropubic device, are included in the  
15 2015 Cochrane review. We've taken a few moments  
16 off the record for you to review that 2015 Cochrane  
17 review.

18 Are you able to answer that question?

19 A. Yes, so looking through their list, the  
20 vast majority of the retropubic-type bottom-up is  
21 TVT. There is Vypro, ULTRAPRO, Prolene light mesh,  
22 and the Okulu study, just going through them --  
23 they are -- there is an occasion one that just says  
24 retropubic, the IV-- IVS similar system, but the

1 vast majority are TVT retropubic, you know, that  
2 are not SPARC or transobturator.

3 Q. So, Doctor, you listed the IVS, the  
4 ULTRAPRO, the Vypro?

5 A. Correct.

6 Q. And those are all bottom-up midurethral  
7 slings listed in the 2015 Cochrane review?

8 A. Correct.

9 There is -- I found -- so there is one  
10 study with an ULTRAPRO Vypro, and then there is one  
11 study with ObTape and DUPS, which I'm not sure  
12 exactly what that is. I'd have to look that up.

13 And there is another one that just says  
14 retropubic. So I'm not sure which study that is.  
15 I'd have to look that up. There is some  
16 nonspecific language in this summary table that I'm  
17 looking at.

18 Q. And, Doctor, when you see a study that  
19 just said "retropubic" and doesn't specify a  
20 particular product, do you find that study to  
21 reliably inform your opinion on whether the  
22 TVT Retropubic device is safe and effective?

23 A. So that study --

24 Q. Doctor, I'm just asking generally. I'm

1 not asking about a specific study.

2 MR. SNELL: Object to speculation and vague on  
3 define.

4 THE WITNESS: Right.

5 So I would have to look at that specific  
6 document to know whether that's a TVT in itself,  
7 but assuming that it's not, since the vast majority  
8 of the studies, the vast majority of the patients  
9 looked at TVT Retropubic, I can reliably use this  
10 as a source for the TVT Retropubic.

11 BY MR. JACKSON:

12 Q. We can switch directions and move on.

13 Doctor, we talked a little bit earlier  
14 about the TVT Retropubic Instructions for Use; do  
15 you remember that?

16 A. Yes.

17 Q. Okay. And do you remember reading the  
18 testimony of an Ethicon employee named Meng Chen  
19 about the Instructions for Use of the TVT IFU?

20 A. Yes.

21 Q. And can you tell me, sitting here, what  
22 you remember about that testimony?

23 A. I believe -- again, I'm not good with the  
24 names but the substance of the IFUs -- I believe it



1 was testimony about what should be included and  
2 what shouldn't be included.

3 (Whereupon, TOMEZSKO Exhibit 11  
4 was marked for identification.)

5 MR. JACKSON: Is that Exhibit 10?

6 THE COURT REPORTER: 11.

7 BY MR. JACKSON:

8 Q. Doctor, do you recall seeing this document  
9 before?

10 A. I believe I have.

11 Q. And, Doctor, it says that Meng Chen is the  
12 associate medical director; do you see that?

13 A. Yes.

14 Q. And that would be the associate medical  
15 director of Ethicon; is that correct?

16 A. Correct.

17 Q. Okay. Have you ever met her?

18 A. No, I have not.

19 Q. Have you reviewed any documents authored  
20 by her in addition to this one?

21 A. I believe I've seen other e-mails  
22 regarding this.

23 Q. Doctor, this message is dated --  
24 I'm sorry. Strike that.

1 Doctor, do you see that this is an e-mail  
2 from Meng Chen dated January 29, 2009?

3 A. Yes.

4 Q. And do you see on that January 29, 2009,  
5 e-mail where Meng Chen is questioning whether or  
6 not the general statement about transitory local  
7 irritation is still sufficient?

8 A. Yes.

9 Q. And do you see what she says above that,  
10 about an hour later? She tells Bryan Lisa, "Pardon  
11 me again. From what I see each day these patient  
12 experiences are not transitory at all"?

13 A. Yes.

14 Q. And do you see that she's talking about  
15 the TVT IFU on tape erosion, exposure and  
16 extrusion?

17 A. Yes.

18 Q. Doctor, do you see toward the top of the  
19 page a mention of Dr. Kirkemo?

20 A. Yes.

21 Q. Do you know who Aaron Kirkemo is?

22 A. I recognize the name, but I forget the  
23 specific position.

24 Q. Doctor, are you aware that Meng Chen

1 recommended that the IFUs be updated to reflect the  
2 kind of calls she was getting about permanent pain  
3 and chronic pain and the inability to have  
4 intercourse?

5 MR. SNELL: Objection. Lacks foundation.  
6 Misstates the evidence.

7 Go ahead.

8 THE WITNESS: Those specific words, I -- I did  
9 see other documents, but I don't remember if that's  
10 what they specifically said.

11 BY MR. JACKSON:

12 Q. Doctor, do you see here where it says  
13 "Meng Chen, M.D., Ph.D.," "The Associate Medical  
14 Director, Worldwide Customer Quality, Ethicon"?

15 A. Yes.

16 Q. Do you disagree with the worldwide medical  
17 director of Ethicon if she said these things need  
18 to be changed to update what is happening?

19 MR. SNELL: Objection. Misstates the evidence.  
20 Go ahead.

21 THE WITNESS: I -- in terms of the IFU and what  
22 it should specifically say, I think these are all  
23 information that implanting surgeons need to know  
24 regardless, and it's part of our general medical

1 knowledge, and it's part of our medical knowledge  
2 just as surgeons and from our literature.

3 So what they feel is important to write in  
4 their IFU, I think, you know, is up to them, but  
5 because this is erosion and dyspareunia or things  
6 that we do know about, whether it's in the IFU or  
7 not, we, as surgeons, need to know that, and we  
8 don't depend on the IFU for that information. We  
9 depend on the research for that information.

10 BY MR. JACKSON:

11 Q. Do you believe that the IFU for the  
12 TVT Retropubic device should contain information on  
13 all known risks?

14 A. I think it should contain information on  
15 known risks. I think it's hard to do all known  
16 risks because that would be an extensive -- that  
17 would be a document like my binder.

18 Q. Doctor, if a company is getting reports in  
19 postmarket surveillance of permanent pain  
20 associated with the TVT Retropubic device, does the  
21 IFU need to be updated to include that information?

22 MR. SNELL: Object. Improper hypothetical.  
23 Lacks foundation.

24 THE WITNESS: So, again, I think that would be

1 up to the company. This is -- as a surgeon, it is  
2 up to us to keep up with the literature and what's  
3 going on at our meetings, what we discuss and what  
4 we're finding as we have experience with patients  
5 regardless of what the IFU says. So, you know,  
6 it's up to the company what it should say, but that  
7 is not our only source of knowledge.

8 BY MR. JACKSON:

9 Q. But I think you agreed earlier, Doctor,  
10 that the IFU is certainly a source of knowledge  
11 that physicians would rely on?

12 A. Right, it is a source of knowledge. Yes,  
13 it is part of the knowledge.

14 Q. Doctor, as someone who is offering  
15 opinions about which warnings should or should not  
16 be included in the IFU for the TVT Retropubic  
17 device, how do you believe the decision should be  
18 made on what should be included?

19 A. So you're saying if it was my job to be  
20 the one to complete the IFU?

21 Q. No.

22 Doctor, I'm saying you're offering  
23 opinions in this case about what information or  
24 warnings should be contained in the TVT IFU,

1 correct?

2 MR. SNELL: I'm going to object. I think  
3 you're misstating her opinion. Her opinion is the  
4 adequacy, sufficiency of the IFU and what risks are  
5 commonly known by surgeons like her. She's not  
6 offering an opinion that she would write the IFU in  
7 a certain manner.

8 BY MR. JACKSON:

9 Q. Doctor, we discussed earlier that the risk  
10 of dyspareunia or painful sexual intercourse is not  
11 listed in the TVT Retropubic IFU, correct?

12 A. Correct.

13 Q. Do you think a woman would want to know if  
14 there is a risk, even if it's not causally related,  
15 that there is a risk that after she gets the  
16 implant, she may experience painful sexual  
17 intercourse?

18 MR. SNELL: Object. Vague. Compound. It asks  
19 for what this undefined woman would or would not  
20 want to know.

21 THE WITNESS: I very much agree that a woman  
22 would want to know whether dyspareunia was a risk  
23 of any surgical procedure that she had, and as a  
24 surgeon, that is my job to ascertain the risk of

1     whatever procedure I'm doing and relay it to the  
2     patient. And, again, that doesn't come from a few  
3     IFU. There are surgeries that we do that have no  
4     IFUs that result in dyspareunia, and we still have  
5     to relay that information. So that is not  
6     IFU-dependent. That is procedure and  
7     surgeon-dependent to relay information to the  
8     patient.

9     BY MR. JACKSON:

10        Q.     Okay. But if Ethicon were getting reports  
11     of dyspareunia in postmarket surveillance, do you  
12     believe Ethicon had a right to update the IFU to  
13     include that information?

14        MR. SNELL:   Form.

15        THE WITNESS:   It has a right to include any  
16     information that it would like, of course.

17     BY MR. JACKSON:

18        Q.     Does Ethicon have an obligation to include  
19     information about painful sexual intercourse that  
20     they've obtained in postmarket surveillance  
21     regarding the TVT Retropubic?

22        MR. SNELL:   Form.   Calls for a legal  
23     conclusion.

24        THE WITNESS:   I don't know what the legal

1 obligation is. That's true. I think in terms of  
2 how I view it -- again, I know all of this  
3 independent of the IFU. So, again, I believe they  
4 should put in what they feel is appropriate for  
5 clinicians to know.

6 BY MR. JACKSON:

7 Q. Well, don't you think as -- I'm sorry.  
8 Strike that.

9 Doctor, you stated earlier that a woman  
10 may require multiple revision surgeries after the  
11 implantation of a TVT Retropubic device, correct?

12 A. Yes.

13 Q. And do you think that's information a  
14 woman -- I'm sorry -- do you think that's  
15 information a patient of yours would want to know  
16 prior to the implantation of the device?

17 MR. SNELL: Same objection. Foundation.

18 Go ahead.

19 THE WITNESS: I do personally think it's  
20 standard of care, and it's standard of care in my  
21 practice to warn patients that, for multiple  
22 different reasons, they may require repeat  
23 operations from this procedure, as well as other  
24 procedures that I do. So that it is something that



1 I do warn patients about.

2 BY MR. JACKSON:

3 Q. But you're not offering any opinions on  
4 whether the risk of multiple revision procedures  
5 should have been included in the IFU by Ethicon?

6 MR. SNELL: Object. Misstates.

7 THE WITNESS: I find that hard to answer.

8 I'm sorry.

9 BY MR. JACKSON:

10 Q. Do you believe Ethicon should have  
11 included the risk of multiple revision surgeries  
12 following the TVT Retropubic procedure in the  
13 TVT Retropubic IFU?

14 A. I think the -- the risk of multiple  
15 revision surgery, being well less than 1 percent,  
16 is such a small risk that I don't think they need  
17 to include every small risk because, again, we know  
18 about these small risks, but that would be up to  
19 Ethicon to decide if they felt it was appropriate.

20 Q. Okay. So, Doctor, I just want to make  
21 sure I'm clear. Is it your testimony that because  
22 it's a risk that -- I am sorry.

23 Doctor, is it your testimony that the risk  
24 of multiple revision surgeries is a risk inherent

1 with all surgeries; is that correct?

2 A. Yes, there is a risk that no matter what  
3 incontinence procedure you have, that you could  
4 need more than one revision surgery or repeat  
5 surgery on that procedure.

6 Q. And, Doctor, that's common knowledge that  
7 any surgeon would know?

8 A. That is common knowledge for any  
9 procedure.

10 Q. But, Doctor, we talked earlier about how  
11 Ethicon warns that you shouldn't implant the  
12 TVT Retropubic in patients who are on  
13 anticoagulation therapy, correct?

14 A. Correct.

15 Q. And that's also common knowledge that any  
16 surgeon would know, correct?

17 A. That is correct.

18 Q. Okay. So is it fair to say that Ethicon  
19 does warn about some things that are common  
20 knowledge?

21 A. Yes, absolutely.

22 Q. But it's your testimony that warning about  
23 multiple revision surgeries after the  
24 TVT Retropubic procedure is not necessary because

1 it's common knowledge?

2 A. I think the content of the IFU is really  
3 difficult because there are so many things that  
4 potentially can be contained. So it's, I would  
5 say, up to them to -- what they include.

6 Q. Doctor, turning to the -- I'm sorry.

7 Doctor, are you aware of brochures for the  
8 TVT Retropubic device?

9 A. Yes.

10 Q. Okay. And, generally speaking, do you  
11 know whether or not the TVT brochure always  
12 disclosed the risk of dyspareunia?

13 A. Oh, I would have to look back at my copies  
14 that I have. I do not think it originally did, but  
15 I'd have to look at the copy.

16 Q. Okay. And, Doctor, we established,  
17 I believe, that the IFU for the TVT Retropubic is  
18 one piece of evidence that an implanting surgeon  
19 such as yourself would consider in forming sort of  
20 your risk-benefit analysis of the TVT Retropubic;  
21 is that fair?

22 MR. SNELL: Object to form. Misstates,  
23 I believe, her testimony.

24 THE WITNESS: It is part of the information

1 that we can include.

2 BY MR. JACKSON:

3 Q. Okay. And is information contained in the  
4 TVT Retropubic brochure also part of the  
5 information you would consider?

6 A. Specifically, I would consider for what?

7 I'm sorry.

8 Q. Doctor, do you read the TVT -- I'm sorry.  
9 Strike that.

10 Doctor, have you read the TVT Retropubic  
11 brochure prior to implanting the TVT Retropubic  
12 device in patients?

13 A. You're talking about the patient  
14 brochure --

15 Q. Yes.

16 A. -- versus the brochure that's given to  
17 providers?

18 Q. Yes.

19 A. Yes, I had looked at the patient brochure  
20 in the past. I am not sure originally whether I  
21 read it prior to or not. I almost think I did not.  
22 I don't think they were available initially. That  
23 is not something that I routinely use. To me  
24 that's not enough information to make any judgments

1 on as a -- as a surgeon.

2 Q. Doctor, would it surprise you to know  
3 that, for example, there are brochures that existed  
4 for a significant period of time that did not  
5 disclose the risk of painful sexual intercourse to  
6 women?

7 A. Would that surprise me?

8 No, it would not surprise me.

9 MR. JACKSON: Mark this as an exhibit.

10 (Whereupon, TOMEZSKO Exhibit 12  
11 was marked for identification.)

12 BY MR. JACKSON:

13 Q. Doctor, do you recall having seen this  
14 document before?

15 A. I believe I have, yes.

16 Q. Do you know who Professor Hausler is?

17 A. I recognize the name. I believe he's one  
18 of the European surgeons.

19 Q. Okay. And do you know who Axel Arnaud is?

20 A. One of the scientific directors.

21 Q. Doctor, do you see where Dr. Hausler  
22 thought that erosions with respect to the TVT mesh  
23 were underreported?

24 A. Yes.

1 Q. Do you agree with the rest of that  
2 statement, where it says "There can be hidden  
3 erosions that are asymptomatic"?

4 MR. SNELL: Object. Form. Incomplete part of  
5 the statement.

6 THE WITNESS: So he wrote that "Most of the  
7 time a hidden erosion is asymptomatic, and neither  
8 the patients, nor their sexual partners have -- if  
9 any complain, but it might happen that a patient  
10 may complain."

11 So do I agree that he might have felt that way?

12 BY MR. JACKSON:

13 Q. Sure.

14 A. You know, per -- Axel said that's what  
15 Dr. Hausler said to him.

16 Q. Doctor, do you believe that asymptomatic  
17 erosions are a possibility following the  
18 implantation of a TVT Retropubic mesh?

19 A. Yes.

20 Q. And do you believe that those asymptomatic  
21 erosions can sometimes turn into symptomatic  
22 erosions many months later?

23 A. That's hard -- that's hard to speak to  
24 because asymptomatic erosion, no one knows is

1     there, and it hasn't been identified. So I can't  
2     say whether that's the one that would turn into a  
3     symptomatic erosion or not. There is no study  
4     that's been done on that.

5           Q.     Doctor, is it fair to say that the body  
6     continues to react to the mesh as long as the mesh  
7     is in the body?

8           MR. SNELL:   Objection. Vague. Overbroad.  
9     Asked and answered.

10          THE WITNESS:   No, I would disagree with that.

11     BY MR. JACKSON:

12          Q.     Doctor, do you see the sentence in the  
13     paragraph that starts "I explained," that says  
14     "I also indicated that we want to be very careful  
15     with any modifications to our tape, since a change  
16     in the mesh would obsolete all the long-term  
17     clinical results we have about the procedure."

18                  Do you see that sentence?

19          A.     Yes, I do.

20          Q.     And can you tell me what, if anything, you  
21     know about that statement?

22          MR. SNELL:   Object.

23          THE WITNESS:   It implies that they don't --  
24     they have to be careful of any changes because then

1 that will make it into a different product.

2 BY MR. JACKSON:

3 Q. When you say "they," you mean Ethicon?

4 A. If Ethicon changed it, it would make a  
5 different product, and then -- and, as surgeons, we  
6 don't automatically say "This product is the same  
7 as that one. They are different." So then we --  
8 you have to start fresh, and they had already had  
9 good success with their product.

10 Q. Doctor, we can put that aside. I'm done  
11 with that one.

12 Doctor, do you know Dr. Roger Goldberg?

13 A. Yes, I do.

14 Q. Does he work at NorthShore Hospital with  
15 you?

16 A. Yes, he does.

17 Q. And do you just know him professionally?

18 A. Yes.

19 Q. Doctor, do you know a Dr. Gregory Bales at  
20 the University of Chicago?

21 A. Yes, yes, I do.

22 Q. And do you just know him professionally?

23 A. Yes, just professionally.

24 Q. And how do you know Dr. Bales



1 specifically?

2 A. Because he's a urologist that works in the  
3 urogynecology sphere. We know each other from  
4 professional organizations, as well as I'm also a  
5 University of Chicago professor, so to speak, and  
6 we train -- he also can help train our fellows, and  
7 most of my interactions have been through our  
8 scientific meetings like AUGS, SUFU, that kind of  
9 thing.

10 MR. JACKSON: I think I have no more questions  
11 at this time. I'll reserve the rest of my time.

12 THE VIDEOGRAPHER: The time is 11:27 a.m., and  
13 we are going off video record.

14 (Brief interruption.)

15 THE VIDEOGRAPHER: The time is 11:32 a.m., and  
16 we are back on the video record.

17 EXAMINATION

18 BY MR. SNELL:

19 Q. Doctor, my name is Burt Snell. We know  
20 each other. I just want to follow up on some of  
21 the questions that plaintiff's counsel asked you.

22 Are you prepared to proceed?

23 A. Yes, I am.

24 Q. Are you prepared to answer my questions to

1 the same degree of truthfulness that you answered  
2 plaintiff's counsel's questions?

3 A. Yes.

4 Q. During your answers to plaintiff's  
5 counsel, at certain times you asked if plaintiff's  
6 counsel would provide certain documents or if he  
7 would allow you to look at certain materials. So  
8 some of what I'm going to ask you about pertains to  
9 the materials to which you were referencing. I'm  
10 just giving you a heads-up where I am going to go.  
11 Okay?

12 A. Yes.

13 Q. First of all, do you recollect plaintiff's  
14 counsel asking you some questions about your  
15 opinions as to the adequacy and content of the  
16 Ethicon TVT sling IFU?

17 A. Yes.

18 Q. And is it your opinion that the Ethicon  
19 TVT IFU is adequate to warn pelvic floor surgeons  
20 of the potential risks specific to the device?

21 A. Yes.

22 Q. Who are the intended users, based upon  
23 your expert review and analysis, of the  
24 TVT Retropubic stress incontinence device?

1           A.     The intended users are surgeons who have  
2     specific training in the treatment of stress  
3     urinary incontinence and specific knowledge of the  
4     treatments and surgeries for stress urinary  
5     incontinence.

6           Q.     Plaintiff's counsel asked you several  
7     questions about whether risks were commonly known  
8     or not to pelvic floor surgeons; do you recollect  
9     that?

10          A.     Yes.

11          Q.     And is that something you investigated and  
12     formulated opinions about, the risks that are  
13     commonly known for stress incontinence surgeons,  
14     including TVT, as to pelvic floor surgeons like  
15     yourself?

16          A.     Yes.

17          Q.     You mentioned the various sources of  
18     knowledge that a surgeon has with regard to these  
19     commonly known risks. Let me ask you this: Are --  
20     is knowledge of those commonly known risks, is that  
21     acquired, if at all, in your medical school?

22          A.     Yes, we start learning about surgical risk  
23     for varied procedures, including stress  
24     incontinence, in medical school.

1 Q. Is a source of that common knowledge that  
2 plaintiff's counsel asked you about with regard to  
3 risk of incontinency procedures, does that flow  
4 from your learning in residency as a pelvic floor  
5 surgeon?

6 A. Yes. Stress incontinence treatment,  
7 surgical and nonsurgical, are part of the core  
8 curriculum of residencies.

9 Q. And same question as to fellowship. Is  
10 the fellowship program that a pelvic floor surgeon  
11 can undergo, do you know whether or not that is a  
12 source of this common knowledge of risk of stress  
13 incontinent surgery?

14 A. Yes, especially in fellowship, that is the  
15 source -- that is where we are learning even a  
16 higher level of all the risk of incontinent  
17 surgeries as well as the procedures. That's where  
18 we absolutely can fine-tune our knowledge of all of  
19 that.

20 Q. Have you investigated or read any of the  
21 core curriculum and curriculum -- expected  
22 curriculum materials for pelvic floor surgeon  
23 residencies and fellowships that pertain to the  
24 risk of not just TVT but also other incontinent

1 surgeries?

2 A. Yes, as part of the core curriculum put  
3 out by the ACGME for residency in OB/GYN, as well  
4 as fellowships in FPMRS, yes, it's part of the core  
5 curriculum that you should know the procedures as  
6 well as the complications.

7 Q. Did you also -- in formulating your  
8 opinions, did you also look out and review or  
9 consider the American Urologic Association's  
10 curriculum regarding stress incontinent surgery  
11 that their residents are expected to know of?

12 A. Yes, I think the American Urologic  
13 Association, AUA, core curriculum includes those  
14 topics for residents, as well as for the medical  
15 students.

16 Q. And were those sources of your foundations  
17 for your opinions as to what risks are commonly  
18 known to pelvic floor surgeons with regard to TVT  
19 and stress incontinent surgeries?

20 A. Yes, they are.

21 Q. Is pain a commonly known potential risk of  
22 stress incontinent surgeries?

23 A. Yes, it is.

24 Q. Is chronic pain a potential risk that's

1 commonly known by pelvic floor surgeons of stress  
2 incontinent surgeries?

3 A. Chronic pain is commonly known. It's very  
4 rare, but it's known that it could possibly happen.

5 Q. And have you seen or did you consider the  
6 regulation on the labeling for medical devices and  
7 whether or not it stated that commonly known risks  
8 need not be included in the Instructions for Use?

9 MR. JACKSON: Objection. Form.

10 THE WITNESS: Yes, I have seen the -- if you're  
11 talking about the FDA regulatory advice on how to  
12 write up, it's -- it said it was up to the judgment  
13 of the person creating it but does not have to  
14 include the commonly known risks.

15 BY MR. SNELL:

16 Q. And have -- did you investigate and have  
17 you opined on what are the commonly known risks to  
18 the intended user pelvic floor surgeon?

19 A. For the sling?

20 Q. Yes.

21 A. Yes, I have.

22 Q. Now, do you have that Ethicon IFU in front  
23 of you, Exhibit 7, that you discussed with  
24 plaintiff's counsel?

1 A. Yes, I do.

2 Q. On the very first page under "Important,"  
3 do you see it says that "The IFU is not a  
4 comprehensive reference to surgical technique for  
5 correcting stress urinary incontinence"?

6 A. Yes, it does say that.

7 Q. And is that something you considered in  
8 formulating your opinion as to whether the IFU was  
9 adequate?

10 A. Yes.

11 Q. Is that something you considered in  
12 formulating your opinions as to whether the  
13 commonly known stress incontinence risk needed to  
14 be in the TVT IFU?

15 A. Yes.

16 Q. A little further down, it states  
17 "Variations in use may occur in specific procedures  
18 due to individual technique and patient anatomy";  
19 do you see that?

20 A. Yes, I do.

21 Q. Is that consistent or inconsistent with  
22 your opinion with regard to the adequacy of the IFU  
23 for how to tension or not tension the TVT?

24 A. Yes.

1 Q. Plaintiff's counsel asked you a question  
2 about whether the TVT IFU contraindicated its use  
3 in women who are obese; do you recollect that?

4 A. Yes.

5 Q. Is there any Level 1 or Level 2 or  
6 reliable evidence that you are aware of that shows  
7 the TVT is not effective in obese women?

8 A. No, there is not.

9 Q. To the contrary, have you investigated the  
10 medical literature to determine whether TVT is  
11 efficacious and safe in women who are normal  
12 weight, overweight or who may be obese?

13 MR. SNELL: Objection. Form.

14 THE WITNESS: Yes, there is literature that  
15 supports the use in varied weight.

16 BY MR. JACKSON:

17 Q. Do you recall plaintiff's counsel asked  
18 you some questions about tensions, and I believe  
19 you testified that you did not want tension of the  
20 TVT once it was placed?

21 A. Correct.

22 Q. If you look at the bottom of this  
23 paragraph, on page number 27, I'm just going to  
24 read it into the record where it's talking about



1 Instructions for Use, actually placing the device.

2 The last paragraph on page 27 says "To  
3 avoid putting tension on the tape, a blunt  
4 instrument (scissors or forceps) should be placed  
5 between the urethra and the tape during removal of  
6 the plastic sheath"; do you see that?

7 A. Yes.

8 Q. "Premature removal of the sheath may make  
9 subsequent adjustments difficult"; do you see that?

10 A. Yes.

11 Q. Is that part of the IFU that you  
12 considered in formulating your opinions?

13 A. Yes.

14 Q. Is that part of the IFU actually  
15 consistent or inconsistent with your opinions that  
16 you do not want to put the TVT in with tension  
17 ultimately?

18 A. I think it's consistent with my opinion.

19 Q. Is it consistent with your technique that  
20 you described to plaintiff's counsel?

21 A. Yes, it is consistent with my technique.

22 Q. Is that something you've learned during  
23 the Ethicon professional education with regard to  
24 TVT and how to space or provide space between the

1 tape and the urethra?

2 A. They did give instruction and basically  
3 made the point of do not tension it, to leave  
4 space.

5 Q. On the first page, this also says that  
6 "The device should be used only by physicians  
7 trained in the surgical treatment of stress urinary  
8 incontinence"?

9 A. Yes.

10 Q. "And specifically in implanting the  
11 Gynecare TVT"; do you see that?

12 A. Yes.

13 Q. Is that something you read and considered  
14 in formulating your opinions as to the adequacy of  
15 the IFU to pelvic floor surgeons?

16 A. Yes.

17 Q. Is that something you also considered in  
18 formulating your opinions as to the adequacy of the  
19 IFU as to pelvic floor surgeons specifically with  
20 regard to the risk that would already be commonly  
21 known?

22 A. Yes.

23 Q. And because the IFU specifically says that  
24 surgeons should be trained or receive some

1 education on the TVT device, do you consider that  
2 professional education, training, the surgical  
3 videos, the slides and other curricula, to  
4 supplement the actual text of the IFU?

5 A. Absolutely.

6 Q. In the warning section, Warning No. 3 says  
7 "Users should be familiar with surgical technique  
8 for bladder neck suspensions and should be  
9 adequately trained in implanting the TVT device";  
10 do you see that?

11 A. I'm sorry. Is it on the same page?

12 Q. I'm sorry. Page 28, the third bullet  
13 point under "Warnings."

14 A. Thank you.

15 Yes, I do see that.

16 Q. And it says "It's important to realize  
17 that TVT is different from the traditional sling  
18 procedure in that the tape should be located  
19 without tension under the midurethra"; do you see  
20 that?

21 A. Yes.

22 Q. Is that an accurate statement, first of  
23 all, that "TVT is different than the traditional  
24 sling procedure in that it's located without

1     tension under the midurethra"?

2             A.     That is true.

3             Q.     And did you consider that in formulating  
4     your opinions as to the adequacy of the TVT IFU?

5             A.     Yes.

6             Q.     Did you consider that in formulating your  
7     opinions as to whether that needed to be warned of,  
8     that there was a clear difference, according to  
9     your analysis and investigation, between the TVT  
10    and the traditional sling in that regard?

11            A.     That's one of the most important points  
12    between -- the difference between the retropubic  
13    TVT and a pubovaginal sling. So that is something  
14    I feel is important to be on the IFU.

15            Q.     The third-to-last bullet point discusses  
16    that "To minimize risk, make sure to place the tape  
17    tension free in the midurethral position"; do you  
18    see that?

19            A.     Yes.

20            Q.     Is that something you considered in  
21    formulating your opinions as to the adequacy of the  
22    TVT IFU?

23            A.     Yes.

24            Q.     Is that consistent or inconsistent with

1 the opinions you expressed earlier with regard to  
2 not wanting to tension the TVT device?

3 A. That's consistent with.

4 Q. You were asked some questions about --  
5 let's go to the mechanical versus the laser --  
6 laser cut issue first.

7 Do you recollect covering that subject  
8 with plaintiff's counsel?

9 A. Yes, I do.

10 Q. Turn to your report at page 32.

11 A. Okay.

12 Q. Page 3, you have a section titled  
13 "Mechanical Versus Laser Cut"?

14 A. Yes.

15 Q. You state that the TVT sling was  
16 mechanically cut beginning between 1998 and 2007,  
17 and that after the introduction of laser cut,  
18 Ethicon continued to make and sell mechanically cut  
19 mesh as well, and that Ethicon still sells both  
20 mechanical cut and laser cut TVT in order to  
21 satisfy surgeon preferences; do you see that?

22 A. Yes, I do.

23 Q. Now, earlier -- let me ask you this: Does  
24 that refresh your recollection as to whether it's

1 your opinion or understanding, based on your review  
2 of the Ethicon documents and other sources, as to  
3 whether the mechanical cut mesh is still available  
4 for the TVT Retropubic device?

5 MR. JACKSON: Objection. Form.

6 THE WITNESS: Yes, it does.

7 BY MR. SNELL:

8 Q. Fair to say you've reviewed a lot of  
9 Ethicon documents?

10 MR. JACKSON: Object to form.

11 THE WITNESS: Yes, I have.

12 BY MR. SNELL:

13 Q. Binders and binders full?

14 A. And thumb drives and thumb drives full.

15 Q. Plaintiff's counsel asked you about any  
16 studies that were specific or addressed the  
17 mechanical cut versus laser cut issue for the mesh;  
18 do you recall that?

19 A. Yes.

20 Q. Did you identify at page 32 and 33 of your  
21 report studies that you were able to find in the  
22 literature that looked at mechanical cut versus  
23 laser cut mesh and whether there was a clinically  
24 significant difference between the two?

1 A. The Neuman -- the Agarwal studies.

2 Q. And --

3 A. Then there is an Thubert study that we  
4 identified that looks specifically at mechanical  
5 versus laser cut.

6 Q. The Thubert study, can you just tell us  
7 does that concern TVT or TVT EXACT?

8 A. TVT versus TVT EXACT.

9 Q. Is that the study you were referencing  
10 earlier to plaintiff's counsel?

11 A. I think so.

12 Q. Did that study show a significant  
13 difference in the exposure rate between the TVT and  
14 newer TVT EXACT laser cut?

15 A. At 12 month follow-up, both of them had a  
16 zero percent exposure rate.

17 Q. Is that a study you considered in  
18 formulating your opinion that there has been no  
19 demonstrated clinically significant difference  
20 between mechanical and laser cut mesh for the  
21 TVT Retropubic device based upon the reliable  
22 literature?

23 A. Yes.

24 Q. In your review of these issues, do you

1 recall seeing the -- do you know what TVT Abbrevio  
2 device is?

3 A. Yes, I do.

4 Q. Do you recall looking at the  
5 de Leval-Waltregny TVT-O versus the TVT Abbrevio  
6 device clinical study that assessed things like  
7 rates of exposure at one year and three years?

8 A. Yes, I do recall that.

9 Q. Is the Abbrevio, do you have an  
10 understanding whether that's only laser cut too?

11 A. That is -- that is only laser cut.

12 Q. And do you have a recollection as to  
13 whether those -- that study that actually compared  
14 the older TVT-O with the TVT Abbrevio, whether it  
15 showed any difference, statistically significant  
16 difference in complication rates pertaining to  
17 rates of exposure or erosion?

18 A. There was no difference in rates of  
19 exposure.

20 Q. Do you also -- is that -- does that form  
21 part of the basis of your opinion that there has  
22 been no reliably demonstrated clinically  
23 significant effect for the mechanical versus laser  
24 cut mesh for TVT?



1 A. Yes, yes.

2 Q. You were asked a question about the  
3 AUGS/SUFU Position Statement and the reference in  
4 your report that TVT is a large bore, lightweight  
5 mesh; do you recall that?

6 A. Yes.

7 Q. Do you -- can you turn to -- I think it's  
8 No. 55 in your binder.

9 A. I think I also have it right here. I have  
10 it right here, yeah.

11 Q. The sentence in the AUGS/SUFU Position  
12 Statement where it references the midurethral sling  
13 as a large pore, macroporous lightweight mesh, can  
14 you find that in that document for me?

15 I believe it's on the second page --

16 A. Yeah.

17 Q. -- under Item No. 1.

18 A. One, yes.

19 Q. And do you see there is a reference after  
20 that?

21 For the record it says "As a knitted  
22 implant for the surgical treatment of SUI,  
23 macroporous, monofilament, lightweight  
24 polypropylene has demonstrated long-term

1 durability, safety and efficacy up to 17 years,"  
2 with a reference eight. Do you see that?

3 A. Yes. That's Dr. Nillson's 17-year study  
4 of TVT Retropubic.

5 Q. Is that the TVT Retropubic device --  
6 specific device you rendered opinions on here  
7 today?

8 A. Yes, it is.

9 Q. And did this physician statement include  
10 any other data on the TVT device?

11 A. Yes, it does.

12 Q. Any Level 1 data?

13 A. Yes, there is. It includes the --  
14 actually, multiple, the Ward study, the Ward-Hilton  
15 study, the Novara review, which includes some of  
16 the TVT --

17 Q. There is a reference to the Ogah-Cochrane  
18 review. I believe you discussed that with  
19 plaintiff's counsel already?

20 A. Right, that was -- Ogah-Cochrane review  
21 yes.

22 Q. Was that the same --

23 A. 2009 Cochrane Review that we were  
24 discussing, yes.

1 Q. And did you investigate whether the larger  
2 pore, supposedly lighter weight meshes for hernia  
3 or prolapse, whether they had been demonstrated to  
4 be as effective as TVT in the application of a  
5 stress incontinence sling?

6 MR. JACKSON: Object to form.

7 THE WITNESS: Yes.

8 BY MR. SNELL:

9 Q. And did you find any data that supported  
10 the conclusion -- strike that.

11 What is your opinion with regard to  
12 whether the ULTRAPRO and Vypro have been  
13 demonstrated to be as safe and effective as TVT?

14 A. In the ULTRAPRO and Vypro study, they  
15 actually had a higher erosion rate, a 4 percent  
16 versus the 2 percent of the TVT Retropubic. So in  
17 my opinion it does not prove it is as safe.

18 Q. And have any of the other meshes, larger  
19 pore or lighter weight absorbable meshes been shown  
20 to be as effective and durable and been studied as  
21 long as TVT?

22 A. No, nothing has.

23 Q. Is it desirable to surgeons, like  
24 yourself, that the TVT has been studied in multiple

1 long-term studies?

2 A. It very much is, yes.

3 MR. SNELL: Let's go off the tape.

4 THE VIDEOGRAPHER: The time is 11:55 a.m. This  
5 is the end of Tape 2, and we are going off the  
6 video record.

7 (Brief interruption.)

8 THE VIDEOGRAPHER: The time is 12:00 noon, and  
9 we are back on the video record.

10 BY MR. SNELL:

11 Q. Doctor, do you recall being asked  
12 questions about the Cochrane Reviews and, for  
13 example, whether data for a device called SPARC was  
14 included?

15 A. Yes.

16 Q. And whether TVT was included as well?

17 A. Yes, I do.

18 Q. Do you have in front of you the  
19 Ogah-Cochrane review?

20 A. Yes, I do.

21 Q. Is that -- first of all, based on the  
22 level of evidence you've described to plaintiff's  
23 counsel, what level of evidence is that?

24 A. It's Level 1.

1 Q. Is there anything higher than Level 1  
2 evidence?

3 A. No.

4 Q. Did you try to formulate your opinions on  
5 the highest level evidence that you could find?

6 A. Yes.

7 Q. Did this Cochrane -- was it a systematic  
8 review of meta-analysis?

9 A. Yes, it is.

10 Q. Did it investigate the efficacy and safety  
11 of the TVT Retropubic device upon which you've  
12 rendered your opinions?

13 A. Yes.

14 Q. Did it compare the actual TVT Retropubic  
15 device to the SPARC device?

16 A. Yes, there is a study in there.

17 Q. What, if anything, did it show -- did the  
18 TVT show as compared to the SPARC?

19 A. The retropubic TVT had a higher success  
20 rate and less voiding dysfunction, less spotter  
21 perforations and less tape erosions than the SPARC  
22 procedure.

23 Q. Is that something you considered in  
24 formulating your opinions in this case?

1 A. Yes.

2 Q. Did that Cochrane review also investigate  
3 the safety of monofilament tapes, like TVT,  
4 compared to multifilament tapes, like others that  
5 use polypropylene, Monocryl, Vicryl or various  
6 multifilament tapes?

7 MR. JACKSON: Objection. Form.

8 MR. SNELL: Strike that.

9 BY MR. SNELL:

10 Q. Did that Cochrane review compare the  
11 monofilament tapes, like TVT, to multifilament  
12 tapes?

13 A. Yes, it did.

14 Q. And what, if anything, did it show you?

15 A. It showed the monofilament tapes -- tapes  
16 showed fewer tape erosions than the multifilament  
17 tapes.

18 Q. What was the rate of erosion with the  
19 monofilament tapes?

20 A. The relative risk for the monofilament  
21 tape was 1.3 percent, so 30 percent higher.

22 Q. So the rate of erosion with the  
23 monofilament was 1.3 percent?

24 A. No, so the relative risk -- I have to look

1 up the exact rate. Sorry. I have to find  
2 Figure 6. Sorry.

3 So this, you know, gives the relative risk  
4 of 1.3 percent, which is usually a 30 percent  
5 higher risk. It doesn't give the exact rate of  
6 erosion.

7 Q. Can I see --

8 A. I don't think.

9 Q. Can I see that Cochrane review?

10 A. Uh-huh. Unless I'm just missing it.

11 Q. It states "Monofilament tapes had fewer  
12 tape erosions (1.3 percent versus 6 percent) with  
13 the RR of 0.25"; do you see that?

14 A. Okay. Sorry. I was looking right past  
15 it.

16 Q. So the rate for the monofilament -- so the  
17 rate for the monofilament tapes was 1.3 percent?

18 A. Correct.

19 And the multifilament was 6 percent.

20 Q. And the RR of 0.25, what does that mean?

21 A. It's a quarter of the percentage,  
22 one fourth.

23 Q. Do you have the Ford-Cochrane review for  
24 2015 that you referenced with plaintiff's counsel

1     handy?

2           A.     Yes, I do.

3           Q.     I just want to turn your attention to  
4     page 10.

5                     You were asked questions about whether the  
6     TVT is a macroporous mesh. Do you recollect that?

7           A.     Yes.

8           Q.     You were shown a document that it included  
9     in a microporous category; do you recall that?

10          A.     Yes.

11          Q.     Is that a document you had seen before  
12     even here today?

13          A.     Yes.

14          Q.     Is that a document that you disagree with?

15          A.     Yes.

16          Q.     And did you consider and look to see  
17     whether the Cochrane review identifies whether TVT  
18     would be a macroporous or a microporous mesh?

19          A.     Yes. According to the Cochrane review,  
20     the Ford review, it's a macroporous Type I mesh.

21          Q.     Is that consistent or inconsistent with  
22     your opinion?

23          A.     That's consistent with my opinion.

24          Q.     Does the Cochrane review state whether



1 macroporous mesh, like the TVT, is biocompatible?

2 A. Yes, it does. It says it has  
3 biocompatibility and low risk of infection.

4 Q. Do you agree with that statement?

5 A. I do.

6 Q. Is that a statement -- is that an opinion  
7 you formulated based upon your own independent  
8 analysis of the literature and data?

9 A. Yes, based on the Level 1 data.

10 Q. Is that an opinion you hold and rely upon  
11 for your earlier expressed opinions that the  
12 reliable data do not show degradation or a  
13 clinically significant long-term chronic  
14 inflammatory effect of the TVT device?

15 A. Yes --

16 MR. JACKSON: Objection. Form.

17 THE WITNESS: Yes, it is.

18 BY MR. SNELL:

19 Q. Can you tell us what level of evidence is  
20 the Ford-Cochrane review?

21 A. Level 1.

22 Q. Do you recall being asked questions about  
23 the pore size of TVT?

24 A. Yes.

1           Q.    I think you earlier stated that the pore  
2   size of TVT was between 1100 and 1300 microns, but  
3   the Moalli study would have measured it more  
4   specifically?

5           A.    Yes.

6           Q.    If the Moalli study identified the pore  
7   size of the TVT Retropubic device at greater than  
8   1300 microns, would that be consistent or  
9   inconsistent with your general understanding and  
10   recollection of what you had viewed its pore size  
11   to be?

12          A.    That's more accurate than my view, of  
13   course.

14          Q.    You were asked questions about specific  
15   studies that would have looked at longer term or  
16   chronic pain; do you recall that topic?

17          A.    Yes.

18          Q.    Is that something you investigated in  
19   formulating your opinions?

20          A.    Yes.

21          Q.    Look at your report at pages 27 and 28.

22                At page 28 you identify a meta-analysis by  
23   Tommaselli?

24          A.    Yes.

1 Q. And you say "It was a systematic review of  
2 long-term studies"; do you see that?

3 A. Yes.

4 Q. Was the TVT device included in that study  
5 or in that meta-analysis?

6 A. Yes, it was.

7 Q. Do you have a recollection of the 3,974  
8 retropubic cases, how many were -- how many of  
9 those was persistent or chronic pain present in?

10 A. 13, which is .3 percent.

11 Q. And do you believe that 0.3 percent to be  
12 a reliable number?

13 A. Yes.

14 Q. What level of evidence is the Tommaselli  
15 systematic review in that analysis?

16 A. That's Level 1 evidence.

17 Q. Do you have a general recollection as to  
18 whether there was one or two TVT Retropubic  
19 long-term studies or multiple ones?

20 A. There is multiple TVT long-term studies.

21 Q. More than 10 or 20?

22 MR. JACKSON: Objection. Form.

23 THE WITNESS: Yes, definitely more than 10.

24

1 BY MR. SNELL:

2 Q. You recall being asked questions about  
3 certain studies and whether they had a primary  
4 end point of safety or dyspareunia or pain?

5 A. Yes.

6 Q. And you identified that primary end points  
7 are something that are specific to a randomized  
8 control trial?

9 A. Yes.

10 Q. Let me ask you this: Did you look at  
11 meta-analyses or database studies whose primary --  
12 one of the primary purporting goals was to report  
13 rates of dyspareunia or pain?

14 A. So in saying "primary end point of the  
15 studies," I'm thinking of the components of the  
16 meta-analysis. So the randomized control studies  
17 were looking at the studies -- especially, like,  
18 just one randomized controlled study, usually, you  
19 can't power it with enough patients. So therefore  
20 you have to have a meta-analysis where they look at  
21 all these different components. So a meta-analysis  
22 primary end point is different than a randomized  
23 controlled trial primary end point. They have  
24 enough volume to actually look at different

1 components.

2 Q. And is that, in your opinion, the best,  
3 most highest level of evidence of what the rate of  
4 that complication would be?

5 A. Yes --

6 MR. JACKSON: Objection. Form.

7 THE WITNESS: Yes. Absolutely.

8 BY MR. SNELL:

9 Q. You reference, for example, at the bottom  
10 of page 28, the Unger 2015 study. Is that a study  
11 of a database -- database-type study?

12 A. Yes, it is.

13 Q. Where the rate of women requiring revision  
14 for pain -- vaginal pain or dyspareunia was  
15 0.2 percent; do you see that?

16 A. Yes.

17 Q. And, actually, is that number consistent  
18 or inconsistent with the Tommaselli number of  
19 0.3 percent long term?

20 A. Consistent.

21 Q. And did you find that number, 0.2 percent,  
22 to be reliable as to the longer term rate of pain  
23 or dyspareunia that requires a reoperation?

24 A. Can you repeat that?

1 Q. Yeah.

2 Did you find the 0.2 percent rate reported  
3 by the Unger paper to be a reliable indicator of  
4 the longer term chronic pain in that database  
5 study?

6 A. Yes, I do.

7 Q. Page 29, you have the Laurikainen 2014  
8 randomized control trial; do you see that?

9 A. Yes.

10 Q. Do you have a recollection as to whether  
11 that was the five-year TVT specific study?

12 A. Yes, I believe it was five years.

13 Q. Did you consider the dyspareunia rate in  
14 that long-term study in formulating your opinions?

15 A. Yes.

16 Q. Svenningsen, you identify a ten-year  
17 study, did it have any rate of long-term  
18 dyspareunia?

19 A. No, it did not.

20 Q. Serati, another ten-year prospective TVT  
21 study, is that something you considered as well?

22 A. Yes.

23 Q. The Nguyen, spelled N-g-u-y-e-n, did they  
24 report that any patients in that database had to

1 have an excision due to pain?

2 A. 1 out of 2,339 for a .02 percent excision  
3 for pain.

4 Q. Is that consistent or inconsistent with  
5 your opinion that the rate of dyspareunia and  
6 chronic pain is below 1 percent for TVT?

7 A. That's consistent.

8 Q. And do you cite other data in your report,  
9 like the Schimpf meta-analysis and the AUA 2012  
10 meta-analysis?

11 A. Yes.

12 Q. And the Schimpf meta-analysis, the  
13 AUA 2012 meta-analysis, what -- what level of  
14 evidence are those, if any?

15 A. They are a Level 1.

16 MR. SNELL: Let's go off the record. Just give  
17 me a quick second.

18 THE VIDEOGRAPHER: The time is 12:15 p.m., and  
19 we are going off the video record.

20 (Brief interruption.)

21 THE VIDEOGRAPHER: The time is 12:20 p.m., and  
22 we are back on the video record.

23 BY MR. SNELL:

24 Q. Doctor, I just have one or two more

1 questions.

2 Do you recall being asked about your  
3 personal use of the TVT Retropubic device?

4 A. Yes, I do.

5 Q. And the need to do a revision or excision  
6 of TVT or other retropubic midurethral slings?

7 A. Yes, I do.

8 Q. Do you have a general estimate as to the  
9 number of TVT Retropubic-specific devices that you  
10 have excised or removed in your career?

11 And I only want your estimate as to  
12 TVT Retropubic.

13 MR. JACKSON: Objection. Form.

14 THE WITNESS: So for TVT Retropubic, I believe  
15 I have only revised or excised about five.

16 BY MR. SNELL:

17 Q. And I believe you earlier identified for  
18 the TVT Retropubic device, your best estimate is  
19 you've performed 1,000 to 1,500 of that device over  
20 your entire career?

21 A. Yes.

22 Q. The five TVTs that you recollect, as your  
23 best estimate, that you had to revise or excise,  
24 how do you give us that estimate of five?



1           A.     I always kept track based on counseling  
2     for my future sling patients, and they were just so  
3     few and far between, it was easy to keep track of  
4     them and tell a patient I have to excise or revise  
5     one once every three or four years.

6           Q.     Last topic.

7                     Plaintiff's counsel asked you some  
8     questions about the rate of mesh exposure with the  
9     TVT device and your disagreement with him that the  
10    rate varies greatly; do you recall that subject?

11          A.     Yes.

12          Q.     Just so the record is clear, at page 27 of  
13    your report, you have a paragraph about what you  
14    believe the rate of exposure to be with TVT; is  
15    that correct or not?

16          A.     Yes, I do.

17          Q.     And are those the particular data sources  
18    you rely upon for your opinion with regard to the  
19    rate of TVT being 1 to 2 percent, with 2 percent  
20    being the most common?

21          A.     Yes, it is.

22          Q.     And are those -- how would you categorize  
23    those literature or sources that you have utilized  
24    in formulating your opinion with regard to the rate

1 of TVT mesh exposure?

2 A. These are primary Level 1 evidence, maybe  
3 a little bit of Level 2 evidence, primarily  
4 Level 1.

5 Q. And do those studies, do they cover both  
6 short- and long-term studies?

7 A. Yes, these cover short and over ten-year  
8 studies.

9 MR. SNELL: That's all the questions I have.  
10 Thank you.

11 FURTHER EXAMINATION

12 BY MR. JACKSON:

13 Q. Doctor, when Ethicon's counsel was just  
14 asking you questions about literature, do you  
15 recall him asking a question about the Nillson  
16 study of 17-year data?

17 A. Yes.

18 Q. And, Doctor, to your knowledge, did that  
19 study involve the mechanically cut TVT Retropubic  
20 device or the laser cut TVT Retropubic device?

21 A. To my knowledge, it's the mechanical cut.

22 Q. And would that study be exclusively  
23 mechanical cut?

24 A. I believe based on the time period -- I'm

1 not 100 percent certain -- but based on the time  
2 period, I believe it's mechanical cut.

3 Q. Doctor, have you reviewed any studies that  
4 compare laser cut mesh and mechanically cut mesh in  
5 the TVT-R device?

6 MR. SNELL: Object. Asked and answered.

7 THE WITNESS: Specifically, just the TVT-R?

8 BY MR. JACKSON:

9 Q. Correct.

10 A. Not the TVT EXACT, you mean?

11 Q. Correct.

12 A. I have in the past. I believe I have in  
13 the past, and right off the top of my head, I can't  
14 think of them right now. I'm sorry.

15 Q. Doctor, when Ethicon's counsel was asking  
16 you questions about literature, do you remember  
17 being asked about a study involving the TVT-O and  
18 the TVT Abbrevio, which looked at rates of exposure?

19 A. Yes.

20 Q. And is it fair to say that study did not  
21 involve the TVT Retropubic device?

22 A. Yes.

23 Q. Doctor, when Ethicon's counsel was asking  
24 you questions about the five revision surgeries you

1 have performed, do you remember that line of  
2 questioning?

3 A. Yes.

4 Q. Okay. Did you report those five revision  
5 surgeries to Ethicon?

6 A. No, I did not.

7 Q. Okay. Did you report those five revision  
8 surgeries to the FDA?

9 A. No, I did not.

10 Q. Okay. Are you aware, Doctor, of  
11 underreporting of adverse events in regards to the  
12 TVT Retropubic device?

13 MR. SNELL: Objection. Foundation.

14 THE WITNESS: The concept of underreporting?

15 BY MR. JACKSON:

16 Q. Yes.

17 A. Yes.

18 Q. And, Doctor, is it fair to say that if  
19 you, yourself, did not report those revision  
20 procedures to Ethicon or the FDA, that there may be  
21 other surgeons who did not report those revision  
22 procedures to Ethicon or the FDA?

23 MR. SNELL: Object. Requires speculation.

24 THE WITNESS: Yes, I would assume there are.

1 BY MR. JACKSON:

2 Q. And, Doctor, all the literature you've  
3 cited can only include known complications,  
4 correct?

5 MR. SNELL: Objection on that one too.

6 BY MR. JACKSON:

7 Q. Doctor, I'm sorry. Let me ask a better  
8 question. Strike that.

9 Doctor, if the author of a study wants to  
10 provide an erosion rate, how do they come up with  
11 that erosion rate?

12 A. So depending on the study, most of the  
13 studies are -- erosion rate is detected on  
14 examination, so physically seeing the patient and  
15 identified on the examination.

16 Q. And, Doctor, the -- sorry. Strike that.

17 Doctor, would the five revision procedures  
18 you performed yourself on TVT Retropubic devices be  
19 included in any of the literature you cited?

20 A. Those patients were not part of studies,  
21 and they were also not erosions.

22 MR. JACKSON: We had previously marked as  
23 Exhibit 5 a binder that the doctor had brought with  
24 her. There is a second binder that she brought on

1 the table. If we could mark that as Exhibit 13.

2 (Whereupon, TOMEZSKO Exhibit 13  
3 was marked for identification.)

4 BY MR. JACKSON:

5 Q. And, Doctor, I believe you also brought  
6 some thumb drives with you today?

7 A. Yes.

8 Q. Could we mark those as Exhibit 14, please.

9 (Whereupon, TOMEZSKO Exhibit 14  
10 was marked for identification.)

11 BY MR. JACKSON:

12 Q. Could you just let us know how many thumb  
13 drives are in that bag?

14 A. There is four.

15 MR. SNELL: Should we mark them collectively A,  
16 B, C, D?

17 MR. JACKSON: Yeah, let's do that.

18 BY MR. JACKSON:

19 Q. And, Doctor, is it your understanding that  
20 the two binders you have in front of you -- I'm  
21 sorry. Strike that.

22 Doctor, the two binders you have in front  
23 of you, can you just identify the materials that  
24 are in what we just marked as Exhibit 13, the

1 second binder? Could you just generally let me  
2 know that what is?

3 A. It's -- some of it is duplicative of the  
4 other binder. It's primarily the -- just more the  
5 research trials, literature.

6 Q. Okay. And, Doctor, I believe you also  
7 brought a box of documents, which is on the floor;  
8 is that correct?

9 A. Yes.

10 Q. And are those copies of Ethicon  
11 depositions and documents?

12 A. Yes.

13 Q. Okay. And are those same documents also  
14 included on the flash drives, to the best of your  
15 knowledge?

16 A. To the best of my knowledge, yes.

17 Q. And, Doctor, do you believe that the  
18 reliance list you provided in this case is  
19 comprehensive of all of the materials you reviewed  
20 in this case?

21 A. To the best of my knowledge.

22 Q. Okay. Thank you.

23 MR. JACKSON: I have no more questions.

24 MR. SNELL: I just have a question or two.

1 FURTHER EXAMINATION

2 BY MR. SNELL:

3 Q. Plaintiff's counsel asked you a question  
4 about your five cases with TVT of the revisions or  
5 whatever type of surgery they were. Did you look  
6 in the literature for studies and databases that  
7 would pick up whether there was a sling release or  
8 not, regardless of whether the surgeon reported it  
9 as an adverse event or whether the patient even  
10 returned back to the same surgeon?

11 MR. JACKSON: Objection. Form.

12 THE WITNESS: Yes. So most of the large  
13 studies are comprehensive in capturing patients or  
14 there are other database studies that basically are  
15 capturing patients through insurance data. So they  
16 are inclusive of whether the patient went back to  
17 the same surgeon or not. So I feel they are very  
18 comprehensive in actually capturing what patients  
19 have revisions or required erosion surgery.

20 BY MR. SNELL:

21 Q. And did you look at those different  
22 database studies to see whether their rates were  
23 consistent or inconsistent with the other data?

24 A. Yes, I do, and they are all consistent



1 with 2 percent.

2 Q. Page 27, you identify -- I'm just going to  
3 give an example -- the Jonsson-Funk 2013 database  
4 study, nine-year study; do you see that?

5 A. Yes.

6 Q. Did you consider that to be a long-term  
7 study?

8 A. Yes.

9 Q. Did you -- was that a study in a large  
10 enough group of patients that it was significant in  
11 your opinion?

12 A. Yes, absolutely.

13 Q. Do you have a recollection of roughly how  
14 many patients were in that study? Was it less than  
15 a 100? More than 1,000?

16 A. I believe that was the 185,000 patients.

17 Q. Pretty big study?

18 A. Very big study.

19 Q. And so do you feel that the rates you've  
20 reported and established in your opinions with  
21 regard to the complications, as well as reoperation  
22 rates, are reliable?

23 A. Yes, I do.

24 MR. SNELL: I have no further questions.

1 MR. JACKSON: I have no further questions.

2 THE VIDEOGRAPHER: Okay. The time is

3 12:32 p.m. This is the end of Tape 3. It's also

4 the end of the deposition of Dr. Janet Tomezsko,

5 and we are going off the video record.

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C E R T I F I C A T E

I, DEANNA AMORE, a Shorthand Reporter and  
notary public, within and for the State of  
Illinois, County of DuPage, do hereby certify:

That JANET TOMEZSKO, M.D., the witness  
whose examination is hereinbefore set forth, was  
first duly sworn by me and that this transcript of  
said testimony is a true record of the testimony  
given by said witness.

I further certify that I am not related to  
any of the parties to this action by blood or  
marriage, and that I am in no way interested in the  
outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my  
hand this 28th day of June, 2016.

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Deanna M. Amore, CSR, RPR

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4 PAGE LINE CHANGE

5 \_\_\_\_\_

6 REASON: \_\_\_\_\_

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8 REASON: \_\_\_\_\_

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10 REASON: \_\_\_\_\_

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ACKNOWLEDGMENT OF DEPONENT

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I, \_\_\_\_\_, do

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hereby certify that I have read the

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foregoing pages, and that the same is

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a correct transcription of the answers

8

given by me to the questions therein

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propounded, except for the corrections or

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changes in form or substance, if any,

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noted in the attached Errata Sheet.

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\_\_\_\_\_  
JANET TOMEZSKO, M.D.

DATE

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Subscribed and sworn

to before me this

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\_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

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My commission expires:\_\_\_\_\_

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\_\_\_\_\_  
Notary Public

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